imposed unless, before the end of that period, the Medicaid agency finds that—

(1) The facility has corrected the deficiencies or is making a good faith effort to achieve compliance with the conditions of participation for ICFs/MR; or

(2) The deficiencies are such that it is necessary to terminate the facility's provider agreement.

(b) *Subsequent termination.* The Medicaid agency must terminate a facility's provider agreement—

(1) Upon the agency's finding that the facility has been unable to achieve compliance with the conditions of participation for ICFs/MR during the period that payments for new admissions have been denied;

(2) Effective the day following the last day of the denial of payments period; and

(3) In accordance with the procedures for appeal of terminations set forth in subpart D of part 431 of this chapter.

[51 FR 24491, July 3, 1986, as amended at 59 FR 56236, Nov. 10, 1994]

Subparts D–F [Reserved]

PART 447—PAYMENTS FOR SERVICES

Subpart A—Payments: General Provisions

Sec.

COST SHARING

ENROLLMENT FEE, PREMIUM OR SIMILAR COST SHARING CHARGE

DEDUCTIBLE, COINSURANCE, CO-PAYMENT OR SIMILAR COST-SHARING CHARGE

FEDERAL FINANCIAL PARTICIPATION

Subpart B—Payment Methods: General Provisions

Subpart C—Payment For Inpatient Hospital and Long-Term Care Facility Services

PAYMENT RATES

FEDERAL FINANCIAL PARTICIPATION

UPPER LIMITS

AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 43 FR 45253, Sept. 29, 1978, unless otherwise noted.

Subpart A—Payments: General Provisions

§ 447.1 Purpose.

This subpart prescribes State plan requirements, FFP limitations and procedures concerning payments made by State Medicaid agencies for Medicaid services.

§ 447.10 Prohibition against reassignment of provider claims.

(a) *Basis and purpose.* This section implements section 1902(a)(32) of the Act which prohibits State payments for Medicaid services to anyone other than a provider or recipient, except in specified circumstances.

(b) *Definitions.* For purposes of this section:

Facility means an institution that furnishes health care services to inpatients.

Factor means an individual or an organization, such as a collection agency or service bureau, that advances money to a provider for accounts receivable that the provider has assigned, sold or transferred to the individual organization for an added fee or a deduction of a portion of the accounts receivable. Factor does not include a business representative as described in paragraph (f) of this section.

Organized health care delivery system means a public or private organization for delivering health services. It includes, but is not limited to, a clinic, a group practice prepaid capitation plan, and a health maintenance organization.

(c) *State plan requirements.* A State plan must provide that the requirements of paragraphs (d) through (h) of this section are met.

(d) *Who may receive payment.* Payment may be made only—

(1) To the provider; or

(2) To the recipient if he is a noncash recipient eligible to receive the payment under § 447.25; or

(3) In accordance with paragraphs (e), (f), and (g) of this section.

(e) *Reassignments.* Payment may be made in accordance with a reassignment from the provider to a government agency or reassignment by a court order.

(f) *Business agents.* Payment may be made to a business agent, such as a billing service or an accounting firm, that furnishes statements and receives payments in the name of the provider, if the agent's compensation for this service is—

(1) Related to the cost of processing the billing;

(2) Not related on a percentage or other basis to the amount that is billed or collected; and

(3) Not dependent upon the collection of the payment.

(g) *Individual practitioners.* Payment may be made to—

(1) The employer of the practitioner, if the practitioner is required as a condition of employment to turn over his fees to the employer;

(2) The facility in which the service is provided, if the practitioner has a contract under which the facility submits the claim; or

(3) A foundation, plan, or similar organization operating an organized health care delivery system, if the practitioner has a contract under which the organization submits the claim.

(h) *Prohibition of payment to factors.* Payment for any service furnished to a recipient by a provider may not be made to or through a factor, either directly or by power of attorney.

[43 FR 45253, Sept. 29, 1978, as amended at 46 FR 42672, Aug. 24, 1981; 61 FR 38398, July 24, 1996]

§ 447.15 Acceptance of State payment as payment in full.

A State plan must provide that the Medicaid agency must limit participation in the Medicaid program to providers who accept, as payment in full, the amounts paid by the agency plus any deductible, coinsurance or copayment required by the plan to be paid by the individual. However, the provider may not deny services to any eligible individual on account of the individual's inability to pay the cost sharing amount imposed by the plan in accordance with § 431.55(g) or § 447.53. The previous sentence does not apply to an individual who is able to pay. An individual's inability to pay does not eliminate his or her liability for the cost sharing charge.

[50 FR 23013, May 30, 1985]

§ 447.20 Provider restrictions: State plan requirements.

A State plan must provide for the following:

(a) In the case of an individual who is eligible for medical assistance under the plan for service(s) for which a third party or parties is liable for payment, if the total amount of the established liability of the third party or parties for the service is—

(1) Equal to or greater than the amount payable under the State plan (which includes, when applicable, cost-sharing payments provided for in §§ 447.53 through 447.56), the provider furnishing the service to the individual may not seek to collect from the individual (or any financially responsible relative or representative of that individual) any payment amount for that service; or

(2) Less than the amount payable under the State plan (including cost sharing payments set forth in §§ 447.53 through 447.56), the provider furnishing the service to that individual may collect from the individual (or any financially responsible relative or representative of the individual) an amount which is the lesser of—

(i) Any cost-sharing payment amount imposed upon the individual under §§ 447.53 through 447.56; or

(ii) An amount which represents the difference between the amount payable under the State plan (which includes, where applicable, cost-sharing payments provided for in §§ 447.53 through 447.56) and the total of the established third party liability for the services.

(b) A provider may not refuse to furnish services covered under the plan to an individual who is eligible for medical assistance under the plan on account of a third party's potential liability for the service(s).

[55 FR 1433, Jan. 16, 1990]

§ 447.21 Reduction of payments to providers.

If a provider seeks to collect from an individual (or any financially responsible relative or representative of that individual) an amount that exceeds an amount specified under § 447.20(a)—

(a) The Medicaid agency may provide for a reduction of any payment amount otherwise due to the provider in addition to any other sanction available to the agency; and

(b) The reduction may be equal to up to three times the amount that the provider sought to collect in violation of § 447.20(a).

[55 FR 1433, Jan. 16, 1990]

§ 447.25 Direct payments to certain recipients for physicians' or dentists' services.

(a) *Basis and purpose.* This section implements section 1905(a) of the Act by prescribing requirements applicable to States making direct payments to certain recipients for physicians' or dentists' services.

(b) *State plan requirements.* Except for groups specified in paragraph (c) of this section, a State may make direct payments to recipients for physicians' or dentists' services. If it does so, the State plan must—

(1) Provide for direct payments; and

(2) Specify the conditions under which payments are made.

(c) *Federal financial participation.* No FFP is available in expenditures for direct payment for physicians' or dentists' services to any recipient—

(1) Who is receiving assistance under the State's approved plan under title I, IV-A, X, XIV or XVI (AABD) of the Act; or

(2) To whom supplemental security benefits are being paid under title XVI of the Act; or

(3) Who is receiving or eligible for a State supplementary payment or would be eligible if he were not in a medical institution, and who is eligible for Medicaid as a categorically needy recipient.

(d) *Federal requirements.* (1) Direct payments to recipients under this section are an alternative to payments directly to providers and are subject to the same conditions; for example, the State's reasonable charge schedules are applicable.

(2) Direct payments must be supported by providers' bills for services.

§ 447.30 Withholding the Federal share of payments to Medicaid providers to recover Medicare overpayments.

(a) *Basis and purpose.* This section implements section 1914 of the Act, which provides for withholding the Federal share of Medicaid payments to a provider if the provider has not arranged to repay Medicare overpayments or has failed to provide information to determine the amount of the overpayments. The intent of the statute and regulations is to facilitate the recovery of Medicare overpayments. The provision enables recovery of overpayments when institutions have reduced participation in Medicare or when physicians and suppliers have submitted few or no claims under Medicare, thus not receiving enough in Medicare reimbursement to permit offset of the overpayment.

(b) *When withholding occurs.* The Federal share of Medicaid payments may be withheld from any provider specified in paragraph (c) of this section to recover Medicare overpayments that CMS has been unable to collect if the provider participates in Medicaid and—

(1) The provider has not made arrangements satisfactory to CMS to repay the Medicare overpayment; or

(2) CMS has been unable to collect information from the provider to determine the existence or amount of Medicare overpayment.

(c) The Federal share of Medicaid payments may be withheld with respect to the following providers:

(1) An institutional provider that has or previously had in effect a Medicare provider agreement under section 1866 of the Act; and

(2) A Medicaid provider who has previously accepted Medicare payment on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act; and during the 12 month period preceding the quarter in which the Federal share is to be withheld for a Medicare overpayment, submitted no claims under Medicare or submitted claims which total less than the amount of overpayment.

(d) *Order to reduce State payment.* (1) CMS may, at its discretion, issue an order to the Medicaid agency of any State that is using the provider's services, to reduce its payment to the provider by the amount specified in paragraph (f) of this section.

(2) The order to reduce payment to the provider will remain in effect until—

(i) The Medicaid agency determines that the overpayment has been completely recovered; or

(ii) CMS terminates the order.

(3) CMS may withhold FFP from any State that does not comply with the order specified in paragraph (d)(1) of this section to reduce payment to the provider and claims FFP for the expenditure on its quarterly expenditure report.

(e) *Notice of withholding.* (1) Before the Federal share of payments may be withheld under this section, CMS will notify the provider and the Medicaid agency of each State that CMS believes may use the overpaid provider's services under Medicaid.

(2) The notice will include the instruction to reduce State payments, as provided under paragraph (d) of this section.

(3) CMS will send the notice referred to in paragraph (e)(1) by certified mail, return receipt requested.

(4) Each Medicaid agency must identify the amount of payment due the provider under Medicaid and give that information to CMS in the next quarterly expenditure report.

(5) The Medicaid agency may appeal any disallowance of FFP resulting from the withholding decision to the Grant Appeals Board, in accordance with 45 CFR part 16.

(f) Amount to be withheld. CMS may require the Medicaid agency to reduce the Federal share of its payment to the provider by the lesser of the following amounts.

(1) The Federal matching share of payments to the provider, or

(2) The total Medicare overpayment to the provider.

(g) *Effective date of withholding.* Withholding of payment will become effective no less than 60 days after the day on which the agency receives notice of withholding.

(h) *Duration of withholding.* No Federal funds are available in expenditures for services that are furnished by a provider specified in paragraph (c) of this section from the date on which the withholding becomes effective until the termination of withholding under paragraph (i) of this section.

(i) *Termination of withholding.* (1) CMS will terminate the order to reduce State payment if it determines that any of the following has occurred:

(i) The Medicare overpayment is completely recovered:

(ii) The institution or person makes an agreement satisfactory to CMS to repay the overpayment; or

(iii) CMS determines that there is no overpayment based on newly acquired evidence or a subsequent audit.

(2) CMS will notify each State that previously received a notice ordering the withholding that the withholding has been terminated.

(j) *Procedures for restoring excess withholding.* If an amount ultimately determined to be in excess of the Medicare overpayment is withheld, CMS will restore any excess funds withheld.

(k) *Recovery of funds from Medicaid agency.* A provider is not entitled to recover from the Medicaid agency the amount of payment withheld by the agency in accordance with a CMS order issued under paragraph (d) of this section.

[50 FR 19688, May 10, 1985; 50 FR 23307, June 3, 1985]

§ 447.31 Withholding Medicare payments to recover Medicaid overpayments.

(a) *Basis and purpose.* Section 1885 of the Act provides authority for CMS to withhold Medicare payments to a Medicaid provider in order to recover Medicaid overpayments to the provider. Section 405.377 of this chapter sets forth the Medicare rules implementing section 1885, and specifies under what circumstances withholding will occur and the providers that are subject to withholding. This section establishes the procedures that the Medicaid agency must follow when requesting that CMS withhold Medicare payments.

(b) *Agency notice to providers.* (1) Before the agency requests recovery of a

Medicaid overpayment through Medicare, the agency must send either or both of the following notices, in addition to that required under paragraph (b)(2) of this section, to the provider.

(i) Notice that—

(A) There has been an overpayment;

(B) Repayment is required; and

(C) The overpayment determination is subject to agency appeal procedures, but we may withhold Medicare payments while an appeal is in progress.

(ii) Notice that—

(A) Information is needed to determine the amount of overpayment if any; and

(B) The provider has at least 30 days in which to supply the information to the agency.

(2) Notice that, 30 days or later from the date of the notice, the agency intends to refer the case to CMS for withholding of Medicare payments.

(3) The agency must send all notices to providers by certified mail, return receipt requested.

(c) *Documentation to be submitted to CMS.* The agency must submit the following information or documentation to CMS (unless otherwise specified) with the request for withholding of Medicare payments.

(1) A statement of the reason that withholding is requested.

(2) The amount of overpayment, type of overpayment, date the overpayment was determined, and the closing date of the pertinent cost reporting period (if applicable).

(3) The quarter in which the overpayment was reported on the quarterly expenditure report (Form CMS 64).

(4) As needed, and upon request from CMS, the names and addresses of the provider's officers and owners for each period that there is an outstanding overpayment.

(5) A statement of assurance that the State agency has met the notice requirements under paragraph (b) of this section.

(6) As needed, and upon request for CMS, copies of notices (under paragraph (b) of this section), and reports of contact or attempted contact with the provider concerning the overpayment, including any reduction or suspension of Medicaid payments made with respect to that overpayment.

(7) A copy of the provider's agreement with the agency under § 431.107 of this chapter.

(d) *Notification to terminate withholding.* (1) If an agency has requested withholding under this section, it must notify CMS if any of the following occurs:

(i) The Medicaid provider makes an agreement satisfactory to the agency to repay the overpayment;

(ii) The Medicaid overpayment is completely recovered; or

(iii) The agency determines that there is no overpayment, based on newly acquired evidence or subsequent audit.

(2) Upon receipt of notification from the State agency, CMS will terminate withholding.

(e) *Accounting for returned overpayment.* The agency must treat as a recovered overpayment the amounts received from CMS to offset Medicaid overpayments.

(f) *Procedures for restoring excess withholding.* The agency must establish procedures satisfactory to CMS to assure the return to the provider of amounts withheld under this section that are ultimately determined to be in excess of overpayments. Those procedures are subject to CMS review.

[50 FR 19689, May 10, 1985, as amended at 61 FR 63749, Dec. 2, 1996]

§ 447.40 Payments for reserving beds in institutions.

(a) The Medicaid agency may make payments to reserve a bed during a recipient's temporary absence from an inpatient facility, if—

(1) The State plan provides for such payments and specifies any limitations on the policy; and

(2) Absences for purposes other than required hospitalization (which cannot be anticipated and planned) are included in the patient's plan of care.

(b) An agency that pays for reserved beds in an inpatient facility may pay less for a reserved bed than an occupied bed if there is a cost differential between the two beds. (Section 1102 of the Act.)

[43 FR 45253, Sept. 29, 1978, as amended at 51 FR 24491, July 3, 1986]

§ 447.45 Timely claims payment.

(a) *Basis and purpose.* This section implements section 1902(a)(37) of the Act by specifying—

(1) State plan requirements for—

(i) Timely processing of claims for payment;

(ii) Prepayment and postpayment claims reviews; and

(2) Conditions under which the Administrator may grant waivers of the time requirements.

(b) *Definitions. Claim* means (1) a bill for services, (2) a line item of service, or (3) all services for one recipient within a bill.

Clean claim means one that can be processed without obtaining additional information from the provider of the service or from a third party. It includes a claim with errors originating in a State's claims system. It does not include a claim from a provider who is under investigation for fraud or abuse, or a claim under review for medical necessity.

A *shared health facility* means any arrangement in which—

(1) Two or more health care practitioners practice their professions at a common physical location;

(2) The practitioners share common waiting areas, examining rooms, treatment rooms, or other space, the services of supporting staff, or equipment;

(3) The practitioners have a person (who may himself be a practitioner)—

(i) Who is in charge of, controls, manages, or supervises substantial aspects of the arrangement or operation for the delivery of health or medical services at the common physical location other than the direct furnishing of professional health care services by the practitioners to their patients; or

(ii) Who makes available to the practitioners the services of supporting staff who are not employees of the practitioners; and

(iii) Who is compensated in whole or in part, for the use of the common physical location or related support services, on a basis related to amounts charged or collected for the services rendered or ordered at the location or on any basis clearly unrelated to the value of the services provided by the person; and

(4) At least one of the practitioners received payments on a fee-for-service basis under titles V, XVIII, and XIX in an amount exceeding $5,000 for any one month during the preceding 12 months or in an aggregate amount exceeding $40,000 during the preceding 12 months.

The term does not include a provider of services (as specified in § 489.2(b) of this chapter), a health maintenance organization (as defined in section 1301(a) of the Public Health Service Act), a hospital cooperative shared services organization meeting the requirements of section 501(e) of the Internal Revenue Code of 1954, or any public entity.

Third party is defined in § 433.135 of this chapter.

(c) *State plan requirements.* A State plan must (1) provide that the requirements of paragraphs (d), (e)(2), (f) and (g) of this section are met; and

(2) Specify the definition of a claim, as provided in paragraph (b) of this section, to be used in meeting the requirements for timely claims payment. The definition may vary by type of service (e.g., physician service, hospital service).

(d) *Timely processing of claims.* (1) The Medicaid agency must require providers to submit all claims no later than 12 months from the date of service.

(2) The agency must pay 90 percent of all clean claims from practitioners, who are in individual or group practice or who practice in shared health facilities, within 30 days of the date of receipt.

(3) The agency must pay 99 percent of all clean claims from practitioners, who are in individual or group practice or who practice in shared health facilities, within 90 days of the date of receipt.

(4) The agency must pay all other claims within 12 months of the date of receipt, except in the following circumstances:

(i) This time limitation does not apply to retroactive adjustments paid to providers who are reimbursed under a retrospective payment system, as defined in § 447.272 of this part.

(ii) If a claim for payment under Medicare has been filed in a timely

manner, the agency may pay a Medicaid claim relating to the same services within 6 months after the agency or the provider receives notice of the disposition of the Medicare claim.

(iii) The time limitation does not apply to claims from providers under investigation for fraud or abuse.

(iv) The agency may make payments at any time in accordance with a court order, to carry out hearing decisions or agency corrective actions taken to resolve a dispute, or to extend the benefits of a hearing decision, corrective action, or court order to others in the same situation as those directly affected by it.

(5) The date of receipt is the date the agency receives the claim, as indicated by its date stamp on the claim.

(6) The date of payment is the date of the check or other form of payment.

(e) *Waivers.* (1) The Administrator may waive the requirements of paragraphs (d) (2) and (3) of this section upon request by an agency if he finds that the agency has shown good faith in trying to meet them. In deciding whether the agency has shown good faith, the Administrator will consider whether the agency has received an unusually high volume of claims which are not clean claims, and whether the agency is making diligent efforts to implement an automated claims processing and information retrieval system.

(2) The agency's request for a waiver must contain a written plan of correction specifying all steps it will take to meet the requirements of this section.

(3) The Administrator will review each case and if he approves a waiver, will specify its expiration date, based on the State's capability and efforts to meet the requirements of this section.

(f) *Prepayment and postpayment claims review.* (1) For all claims, the agency must conduct prepayment claims review consisting of—

(i) Verification that the recipient was included in the eligibility file and that the provider was authorized to furnish the service at the time the service was furnished;

(ii) Checks that the number of visits and services delivered are logically consistent with the recipient's characteristics and circumstances, such as type of illness, age, sex, service location;

(iii) Verification that the claim does not duplicate or conflict with one reviewed previously or currently being reviewed;

(iv) Verification that a payment does not exceed any reimbursement rates or limits in the State plan; and

(v) Checks for third party liability within the requirements of § 433.137 of this chapter.

(2) The agency must conduct postpayment claims review that meets the requirements of parts 455 and 456 of this chapter, dealing with fraud and utilization control.

(g) *Reports.* The agency must provide any reports and documentation on compliance with this section that the Administrator may require.

(Secs. 1102 and 1902(a)(37) of the Social Security Act (42 U.S.C. 1302, 1396a(a)(37)))

[44 FR 30344, May 25, 1979, as amended at 55 FR 1434, Jan. 16, 1990]

§ 447.46 Timely claims payment by MCOs.

(a) *Basis and scope.* This section implements section 1932(f) of the Act by specifying the rules and exceptions for prompt payment of claims by MCOs.

(b) *Definitions.* ''Claim'' and ''clean claim'' have the meaning given those terms in § 447.45.

(c) *Contract requirements*—(1) *Basic rule.* A contract with an MCO must provide that the organization will meet the requirements of §§ 447.45(d)(2) and (d)(3), and abide by the specifications of §§ 447.45(d)(5) and (d)(6).

(2) *Exception.* The MCO and its providers may, by mutual agreement, establish an alternative payment schedule.

(3) *Alternative schedule.* Any alternative schedule must be stipulated in the contract.

[67 FR 41115, June 14, 2002]

COST SHARING

§ 447.50 Cost sharing: Basis and purpose.

(a) Section 1902(a)(14) of the Act permits States to require certain recipients to share some of the costs of Medicaid by imposing upon them such payments as enrollment fees, premiums,

deductibles, coinsurance, co-payments, or similar cost sharing charges. For States that impose cost sharing payments, §§ 447.51 through 447.59 prescribe State plan requirements and options for cost sharing, specify the standards and conditions under which States may impose cost sharing, set forth minimum amounts and the methods for determining maximum amounts, and prescribe conditions for FFP that relate to cost sharing requirements.

ENROLLMENT FEE, PREMIUM OR SIMILAR COST SHARING CHARGE

§ 447.51 Requirements and options.

(a) The plan must provide that the Medicaid agency does not impose any enrollment fee, premium, or similar charge upon categorically needy individuals, as defined in §§ 435.4 and 436.3 of this subchapter, for any services available under the plan.

(b) The plan may impose an enrollment fee, premium, or similar charge on medically needy individuals, as defined in §§ 435.4 and 436.3 of this subchapter, for any services available under the plan.

(c) For each charge imposed under paragraph (b) of this section, the plan must specify—

(1) The amount of the charge;

(2) The period of liability for the charge; and

(3) The consequences for an individual who does not pay.

(d) The plan must provide that any charge imposed under paragraph (b) of this section is related to total gross family income as set forth under § 447.52.

§ 447.52 Minimum and maximum income-related charges.

For the purpose of relating the amount of an enrollment fee, premium, or similar charge to total gross family income, as required under § 447.51(d), the following rules apply:

(a) *Minimum charge.* A charge of at least $1.00 per month is imposed on each—

(1) One- or two-person family with monthly gross income of $150 or less;

(2) Three- or four-person family with monthly gross income of $300 or less; and

(3) Five- or more-person family with monthly gross income of $350 or less.

(b) *Maximum charge.* Any charge related to gross family income that is above the minimum listed in paragraph (a) of this section may not exceed the standards shown in the following table:

MAXIMUM MONTHLY CHARGE

Gross family income (per month)	Family size		
	1 or 2	3 or 4	5 or more
$150 or less	$1	$1	$1
$151 or $200	2	1	1
$201 to $250	3	1	1
$251 to $300	4	1	1
$301 to $350	5	2	1
$351 to $400	6	3	2
$401 to $450	7	4	3
$451 to $500	8	5	4
$501 to $550	9	6	5
$551 to $600	10	7	6
$601 to $650	11	8	7
$651 to $700	12	9	8
$701 to $750	13	10	9
$751 to $800	14	11	10
$801 to $850	15	12	11
$851 to $900	16	13	12
$901 to $950	17	14	13
$951 to $1,000	18	15	14
More than $1,000	19	16	15

(c) *Income-related charges.* The agency must impose an appropriately higher charge for each higher level of family income, within the maximum amounts specified in paragraph (b) of this section.

[43 FR 45253, Sept. 29, 1978, as amended at 45 FR 24889, Apr. 11, 1980]

DEDUCTIBLE, COINSURANCE, CO-PAYMENT OR SIMILAR COST-SHARING CHARGE

§ 447.53 Applicability; specification; multiple charges.

(a) *Basic requirements.* Except as specified in paragraph (b) of this section, the plan may impose a nominal deductible, coinsurance, copayment, or similar charge upon categorically and medically needy individuals for any service under the plan.

(b) *Exclusions from cost sharing.* The plan may not provide for impositions of a deductible, coinsurance, copayment, or similar charge upon categorically or medically needy individuals for the following:

(1) *Children.* Services furnished to individuals under 18 years of age (and, at the option of the State, individuals under 21, 20, or 19 years of age, or any

reasonable category of individuals 18 years of age or over but under 21) are excluded from cost sharing.

(2) *Pregnant women.* Services furnished to pregnant women if such services related to the pregnancy, or to any other medical condition which may complicate the pregnancy are excluded from cost sharing obligations. These services include routine prenatal care, labor and delivery, routine postpartum care, family planning services, complications of pregnancy or delivery likely to affect the pregnancy, such as hypertension, diabetes, urinary tract infection, and services furnished during the postpartum period for conditions or complications related to the pregnancy. The postpartum period is the immediate postpartum period which begins on the last day of pregnancy and extends through the end of the month in which the 60-day period following termination of pregnancy ends. States may further exclude from cost sharing all services furnished to pregnant women if they desire.

(3) *Institutionalized individuals.* Services furnished to any individual who is an inpatient in a hospital, long-term care facility, or other medical institution if the individual is required (pursuant to § 435.725, § 435,733, § 435.832, or § 436.832), as a condition of receiving services in the institution, to spend all but a minimal amount of his income required for personal needs, for medical care costs are excluded from cost sharing.

(4) *Emergency services.* Services provided in a hospital, clinic, office, or other facility that is equipped to furnish the required care, after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that the absence of immediate medical attention could reasonably be expected to result in—

(i) Placing the patient's health in serious jeopardy;

(ii) Serious impairment to bodily functions; or

(iii) Serious dysfunction of any bodily organ or part.

(5) *Family planning.* Family planning services and supplies furnished to individuals of child-bearing age are excluded from cost sharing.

(c) *Prohibition against multiple charges.* For any service, the plan may not impose more than one type of charge referred to in paragraph (a) of this section.

(d) *State plan specifications.* For each charge imposed under this section, the plan must specify—

(1) The service for which the charge is made;

(2) The amount of the charge;

(3) The basis for determining the charge;

(4) The basis for determining whether an individual is unable to pay the charge and the means by which such an individual will be identified to providers; and

(5) The procedures for implementing and enforcing the exclusions from cost sharing found in paragraph (b) of this section.

(e) No provider may deny services, to an individual who is eligible for the services, on account of the individual's inability to pay the cost sharing.

[43 FR 45253, Sept. 29, 1978, as amended at 47 FR 21051, May 17, 1982; 48 FR 5736, Jan. 8, 1983; 50 FR 23013, May 30, 1985; 55 FR 48611, Nov. 21, 1990; 55 FR 52130, Dec. 19, 1990; 67 FR 41116, June 14, 2002]

§ 447.54 Maximum allowable charges.

(a) *Non-institutional services.* Except as specified in paragraph (b), for non-institutional services, the plan must provide that—

(1) Any deductible it imposes does not exceed $2.00 per month per family for each period of Medicaid eligibility. For example, if Medicaid eligibility is certified for a 3-month period, the maximum deductible which may be imposed on a family for that period of eligibility is $6.00;

(2) Any coinsurance rate it imposes does not exceed 5 percent of the payment the agency makes for the services; and

(3) Any co-payments it imposes do not exceed the amounts shown in the following table:

States payment for the service	Maximum copayment chargeable to recipient
$10 or less	$.50
$10.01 to $25	1.00

States payment for the service	Maximum copayment chargeable to recipient
$25.01 to $50	2.00
$50.01 or more	3.00

(b) *Waiver of the requirement that cost sharing amounts be nominal.* Upon approval from CMS, the requirement that cost sharing charges must be nominal may be waived, in accordance with section 431.55(g) for nonemergency services furnished in a hospital emergency room.

(c) *Institutional services.* For institutional services, the plan must provide that the maximum deductible, coinsurance or co-payment charge for each admission does not exceed 50 percent of the payment the agency makes for the first day of care in the institution.

(d) *Cumulative maximum.* The plan may provide for a cumulative maximum amount for all deductible, coinsurance or co-payment charges that it imposes on any family during a specified period of time.

[48 FR 5736, Jan. 8, 1983]

§ 447.55 Standard co-payment.

(a) The plan may provide for a standard, or fixed, co-payment amount for any service.

(b) This standard copayment amount for any service may be determined by applying the maximum co-payment amounts specified in § 447.54 (a) and (b) to the agency's average or typical payment for that service. For example, if the agency's typical payment for prescribed drugs is $4 to $5 per prescription, the agency might set a standard copayment of $0.50 per prescription.

§ 447.56 Income-related charges.

Subject to the maximum allowable charges specified in § 447.54 (a) and (b), the plan may provide for income-related deductible, coinsurance or copayment charges. For example, an agency may impose a higher charge on medically needy recipients than it imposes upon categorically needy recipients.

§ 447.57 Restrictions on payments to providers.

(a) The plan must provide that the agency does not increase the payment it makes to any provider to offset uncollected amounts for deductibles, coinsurance, copayments or similar charges that the provider has waived or are uncollectable, except as permitted under paragraph (b) of this section.

(b) For those providers that the agency reimburses under Medicare reasonable cost reimbursement principles, in accordance with subpart B of this part, an agency may increase its payment to offset uncollected deductible, coinsurance, copayment, or similar charges that are bad debts of providers.

§ 447.58 Payments to prepaid capitation organizations.

If the agency contracts with a prepaid capitation organization that does not impose the agency's deductibles, coinsurance, co-payments or similar charges on its recipient members, the plan must provide that the agency calculates its payments to the organization as if those cost sharing charges were collected.

[48 FR 5736, Jan. 8, 1983, as amended at 67 FR 41116, June 14, 2002]

FEDERAL FINANCIAL PARTICIPATION

§ 447.59 FFP: Conditions relating to cost sharing.

No FFP in the State's expenditures for services is available for—

(a) Any cost sharing amounts that recipients should have paid as enrollment fees, premiums, deductibles, coinsurance, copayments, or similar charges under §§ 447.50 through 447.58 (except for amounts that the agency pays as bad debts of providers under § 447.57); and

(b) Any amounts paid by the agency on behalf of ineligible individuals, whether or not the individual had paid any required premium or enrollment fee.

§ 447.60 Cost-sharing requirements for services furnished by MCOs.

Contracts with MCOs must provide that any cost-sharing charges the MCO imposes on Medicaid enrollees are in accordance with the requirements set forth in §§ 447.50 and 447.53 through

447.58 for cost-sharing charges imposed by the State agency.

[67 FR 41116, June 14, 2002]

§ 447.88 Options for claiming FFP payment for section 1920A presumptive eligibility medical assistance payments.

(a) The FMAP rate for medical assistance payments made available to a child during a presumptive eligibility period under section 1920A of the Act is the regular FMAP under title XIX, based on the category of medical assistance; that is, the enhanced FMAP is not available for section 1920A presumptive eligibility expenditures.

(b) States have the following 3 options for identifying Medicaid section 1920A presumptive eligibility expenditures and the application of payments for those expenditures:

(1) A State may identify Medicaid section 1920A presumptive eligibility expenditures in the quarter expended with no further adjustment based on the results of a subsequent actual eligibility determination (if any).

(2) A State may identify Medicaid section 1920A presumptive eligibility expenditures in the quarter expended but may adjust reported expenditures based on results of the actual eligibility determination (if any) to reflect the actual eligibility status of the individual, if other than presumptively eligible.

(3) A State may elect to delay submission of claims for payments of section 1920A presumptive eligibility expenditures until after the actual eligibility determination (if any) is made and, at that time identify such expenditures based on the actual eligibility status of individuals if other than presumptively eligible. At that time, the State would, as appropriate, recategorize the medical assistance expenditures made during the section 1920A presumptive eligibility period based on the results of the actual eligibility determination, and claim them appropriately.

[65 FR 33622, May 24, 2000]

Subpart B—Payment Methods: General Provisions

§ 447.200 Basis and purpose.

This subpart prescribes State plan requirements for setting payment rates to implement, in part, section 1902(a)(30) of the Act, which requires that payments for services be consistent with efficiency, economy, and quality of care.

[46 FR 48560, Oct. 1, 1981]

§ 447.201 State plan requirements.

(a) A State plan must provide that the requirements in this subpart are met.

(b) The plan must describe the policy and the methods to be used in setting payment rates for each type of service included in the State's Medicaid program.

§ 447.202 Audits.

The Medicaid agency must assure appropriate audit of records if payment is based on costs of services or on a fee plus cost of materials.

§ 447.203 Documentation of payment rates.

(a) The agency must maintain documentation of payment rates and make it available to HHS upon request.

(b) The agency must record, in State manuals or other official files, the following information for increases in payment rates for individual practitioner services:

(1) An estimate of the percentile of the range of customary charges to which the revised payment structure equates and a description of the methods used to make the estimate.

(2) An estimate of the composite average percentage increase of the revised payment rates over the preceding rates.

§ 447.204 Encouragement of provider participation.

The agency's payments must be sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population.

§ 447.205 Public notice of changes in Statewide methods and standards for setting payment rates.

(a) *When notice is required.* Except as specified in paragraph (b) of this section, the agency must provide public notice of any significant proposed change in its methods and standards for setting payment rates for services.

(b) *When notice is not required.* Notice is not required if—

(1) The change is being made to conform to Medicare methods or levels of reimbursement;

(2) The change is required by court order; or

(3) The change is based on changes in wholesalers' or manufacturers' prices of drugs or materials, if the agency's reimbursement system is based on material cost plus a professional fee.

(c) *Content of notice.* The notice must—

(1) Describe the proposed change in methods and standards;

(2) Give an estimate of any expected increase or decrease in annual aggregate expenditures;

(3) Explain why the agency is changing its methods and standards;

(4) Identify a local agency in each county (such as the social services agency or health department) where copies of the proposed changes are available for public review;

(5) Give an address where written comments may be sent and reviewed by the public; and

(6) If there are public hearings, give the location, date and time for hearings or tell how this information may be obtained.

(d) *Publication of notice.* The notice must—

(1) Be published before the proposed effective date of the change; and

(2) Appear as a public announcement in one of the following publications:

(i) A State register similar to the FEDERAL REGISTER.

(ii) The newspaper of widest circulation in each city with a population of 50,000 or more.

(iii) The newspaper of widest circulation in the State, if there is no city with a population of 50,000 or more.

[46 FR 58680, Dec. 3, 1981; 47 FR 8567, Mar. 1, 1982, as amended at 48 FR 56057, Dec. 19, 1983]

§ 447.206 Cost limit for providers operated by units of government.

(a) *Scope.* This section applies to payments made to health care providers that are operated by units of government as defined in § 433.50(a)(1) of this chapter.

(b) *Exceptions.* The limitation in paragraph (c) of this section does not apply to:

(1) Indian Health Services facilities and tribal facilities that are funded through the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638);

(2) Managed Care Organizations (MCOs), Prepaid Inpatient

Health Plans (PIHPs), and Prepaid Ambulatory Health Plans (PAHPs) which are organized and operating in accordance with the provisions of 42 CFR 438;

(3) Federally Qualified Health Centers (FQHCs) and Rural

Health Clinics (RHCs) reimbursed in accordance with Section 1902(bb) of the Act; and

(4) *Disproportionate share hospital payments.* The limitation in paragraph (c) of this section does not apply to payment adjustments made under section 1923 of the Act that are made under a State plan to hospitals found to serve a disproportionate number of low-income patients with special needs as provided in section 1902(a)(13)(A)(iv) of the Act. Disproportionate share hospital (DSH) payments are subject to the following limits:

(i) The aggregate DSH limit using the Federal share of the DSH limit under section 1923(f) of the Act.

(ii) The hospital-specific DSH limit in section 1923(g) of the Act.

(iii) The aggregate DSH limit for institutions for mental disease (IMDs) under section 1923(h) of the Act.

(a) *General rules.* (1) All health care providers that are operated by units of government are limited to reimbursement not in excess of the individual health care provider's cost of providing covered Medicaid services to eligible Medicaid recipients.

(2) Reasonable methods of identifying and allocating costs to Medicaid will be determined by the Secretary in accordance with sections 1902, 1903, and 1905 of the Act, as well as 45 CFR 92.22

and Medicare cost principles when applicable.

(3) Institutional governmentally-operated health care providers (i.e., hospitals, nursing facilities, and ICFs/MR) are required to provide the State with data extracted from primary source documents as well as copies of the source documents. These source documents would include the health care provider's Medicare cost report (or Medicaid cost report for intermediate nursing facility care and ICFs/MR consistent with Medicare cost reporting principles, and audited financial statements that will be used in conjunction with information provided by the States' Medicaid Management Information System (MMIS).

(4) Medicaid costs for non-institutional governmentally-operated health care providers must be supported by auditable documentation in a form approved by the Secretary that is consistent with § 433.51(b)(1) through (b)(4) of this chapter.

(d) *Use of certified public expenditures.* This paragraph applies when States use a cost reimbursement methodology funded by certified public expenditures.

(1) In accordance with paragraph (c) of this section, each provider must submit annually a cost report to the Medicaid agency that reflects the individual provider's cost of serving Medicaid recipients during the year.

(2) States may utilize most recently filed cost reports to develop interim rates and may trend those interim rates by an applicable health care-related index. Interim reconciliations must be performed by reconciling the interim Medicaid payment rates to the filed cost report for the spending year in which interim payment rates were made.

(3) Final reconciliation must be performed annually by reconciling any interim payments to the finalized cost report for the spending year in which any interim payment rates were made.

(4) Non-institutional governmentally-operated health care providers must utilize a cost report, approved by the Secretary, beginning in their Medicaid State plan rate year 2009. Interim rates set by States for purposes of Medicaid payments funded by certified public expenditures in Medicaid State plan rate year 2009 must be calculated based on cost data from at least one quarter of their Medicaid State plan rate year 2008 documented in accordance with the cost report approved by the Secretary. Existing certified public expenditure methodologies can be used to make Medicaid payments during Medicaid State plan rate year 2008.

(e) *Payments not funded by certified public expenditures.* This paragraph applies to payments made to providers operated by units of government that are not funded by certified public expenditures. In accordance with paragraph (c) of this section, each provider must submit annually a cost report to the Medicaid agency that reflects the individual provider's cost of serving Medicaid recipients during the year. The Medicaid agency must review the cost report to determine that costs on the report were properly allocated to Medicaid and verify that Medicaid payments to the provider during the year did not exceed the provider's cost.

(f) *Overpayments.* If, under paragraph (d) or (e) of this section, it is determined that a governmentally-operated health care provider received an overpayment, amounts related to the overpayment will be properly credited to the Federal government, in accordance with part 433, subpart F of this chapter.

(g) *Compliance dates.* Initial compliance dates have been separately established for institutional and non-institutional Medicaid providers operated by units of government. Following initial compliance dates, ongoing compliance will be consistent for all providers operated by units of government. A State must comply with the Medicaid cost limit described in paragraph (c) of this section in accordance with the timeframes and requirements in paragraphs (g)(1) through (g)(3) of this section.

(1) *Initial Compliance for Institutional Govermentally-Operated Health Care Providers.* For each State, compliance with the Medicaid cost limit described in paragraph (c) of this section applicable to institutional governmentally-operated health care providers begins with the Medicaid State plan rate year 2008. A State's review of Medicaid payments made to institutional governmentally-

operated health care providers to ensure compliance with the Medicaid cost limit during Medicaid State plan rate year 2008 must be completed no later than the last day of federal fiscal year 2010 (September 30, 2010). The State must submit to CMS a summary report of the findings of this review by the last day of calendar year of 2010 (December 31, 2010). For any cost reports that are not finalized, the State should use the ''as filed'' cost report and indicate such in the summary report to CMS. The State should then submit a corrected summary report to CMS within 30 days of the finalization of the cost report.

(2) *Initial Compliance for Non-Institutional Governmentally-Operated Health Care Providers.* For each State, compliance with the cost limit described in paragraph (c) of this section applicable to non-institutional governmentally-operated health care providers begins with the Medicaid State plan rate year 2009. A State's review of Medicaid payments made to non-institutional governmentally-operated health care providers to ensure compliance with the Medicaid cost limit during Medicaid State plan rate year 2009 must be completed no later than the last day of federal fiscal year 2011 (September 30, 2011). The State must submit to CMS a summary report of the findings of this review by the last day of calendar year of 2011 (December 31, 2011).

(3) *Ongoing Compliance for Institutional and Non-Institutional Governmentally-Operated Health Care Providers.* Each subsequent State review of Medicaid payments made to governmentally-operated health care providers, after the Medicaid State plan rate years identified in paragraphs (g)(1) and (g)(2) of this section, must be performed annually and completed by the last day of the federal fiscal year ending two years from the Medicaid State Plan rate year under review. Each State must submit a summary report to CMS demonstrating the results of the State's review of Medicaid payments to ensure compliance with the Medicaid cost limit applicable to governmentally-operated health care providers by the last day of the calendar year ending two years from the Medicaid State Plan rate year under review.

(i) For any cost reports that are not finalized at the time the State performs the review of Medicaid payments to institutional governmentally-operated health care providers, the State should use the ''as filed'' cost report and indicate such in the summary report to CMS. The State should then submit a corrected summary report to CMS within 30 days of the finalization of the cost report.

[72 FR 29833, May 29, 2007]

§ 447.207 Retention of payments.

(a) Payment methodologies must permit the provider to receive and retain the full amount of the total computable payment for services furnished under the approved State plan (or the approved provisions of a waiver or demonstration if applicable). The Secretary will determine compliance with this provision by examining any associated transactions that are related to the provider's total computable payment to ensure that the State's claimed expenditure, which serves as the basis for Federal Financial Participation, is equal to the State's net expenditure, and that the full amount of the non-Federal share of the payment has been satisfied.

(b) *Exceptions.* Provisions of paragraph (a) of this section specifically do not pertain to:

(1) Use of Medicaid revenues to fund payments that are normal operating expenses of conducting business, such as payments related to taxes (including permissible health-care related taxes), fees, or business relationships with governments unrelated to Medicaid in which there is no connection to Medicaid payment.

(2) Payments authorized by Sections 701(d) and 705 of the Benefits Improvement Act of 2000 (BIPA).

[72 FR 29834, May 29, 2007]

Subpart C—Payment for Inpatient Hospital and Long-Term Care Facility Services

SOURCE: 46 FR 47971, Sept. 30, 1981, unless otherwise noted.

§ 447.250 Basis and purpose.

(a) This subpart implements section 1902(a)(13)(A) of the Act, which requires that the State plan provide for payment for hospital and long-term care facility services through the use of rates that the State finds, and makes assurances satisfactory to the Secretary, are reasonable and adequate to meet the costs that must be incurred by efficiently and economically operated facilities to provide services in conformity with State and Federal laws, regulations, and quality and safety standards.

(b) Section 447.253(a)(2) implements section 1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy, and quality of care;

(c) Sections 447.253 (c) and (d) implement sections 1902(a)(13)(B) and 1902(a)(13)(C) of the Act, which require a State Medicaid agency to make certain assurances to the Secretary regarding increases in payments resulting solely from changes in ownerships of hospitals, NFs, and ICFs/MR.

(d) Section 447.271 implements section 1903(i)(3) of the Act, which requires that payments for inpatient hospital services not exceed the hospital's customary charges.

(e) Section 447.280 implements section 1913(b) of the Act, which concerns reimbursement for long-term care services furnished by swing-bed hospitals.

[48 FR 56057, Dec. 19, 1983, as amended at 57 FR 43921, Sept. 23, 1992]

PAYMENT RATES

§ 447.251 Definitions.

For the purposes of this subpart—

Long-term care facility services means intermediate care facility services for the mentally retarded (ICF/MR) and nursing facility (NF) services.

Provider means an institution that furnishes inpatient hospital services or an institution that furnishes long-term care facility services.

[46 FR 47971, Sept. 30, 1981, as amended at 54 FR 5359, Feb. 2, 1989; 56 FR 48867, Sept. 26, 1991]

§ 447.252 State plan requirements.

(a) The plan must provide that the requirements of this subpart are met.

(b) The plan must specify comprehensively the methods and standards used by the agency to set payment rates in a manner consistent with § 430.10 of this chapter.

(c) If the agency chooses to apply the cost limits established under Medicare (see § 413.30 of this chapter) on an individual provider basis, the plan must specify this requirement.

(Approved by the Office of Management and Budget under control number 0938–0193)

[48 FR 56058, Dec. 19, 1983, as amended at 51 FR 34833, Sept. 30, 1986]

§ 447.253 Other requirements.

(a) *State assurances.* In order to receive CMS approval of a State plan change in payment methods and standards, the Medicaid agency must make assurances satisfactory to CMS that the requirements set forth in paragraphs (b) through (i) of this section are being met, must submit the related information required by § 447.255 of this subpart, and must comply with all other requirements of this subpart.

(b) *Findings.* Whenever the Medicaid agency makes a change in its methods and standards, but not less often than annually, the agency must make the following findings:

(1) *Payment rates.* (i) The Medicaid agency pays for inpatient hospital services and long-term care facility services through the use of rates that are reasonable and adequate to meet the costs that must be incurred by efficiently and economically operated providers to provide services in conformity with applicable State and Federal laws, regulations, and quality and safety standards.

(ii) With respect to inpatient hospital services—

(A) The methods and standards used to determine payment rates take into account the situation of hospitals which serve a disproportionate number of low income patients with special needs;

(B) If a State elects in its State plan to cover inappropriate level of care services (that is, services furnished to hospital inpatients who require a lower

covered level of care such as skilled nursing or intermediate care services) under conditions similar to those described in section 1861(v)(1)(G) of the Act, the methods and standards used to determine payment rates must specify that the payments for this type of care must be made at rates lower than those for inpatient hospital level of care services, reflecting the level of care actually received, in a manner consistent with section 1861(v)(1)(G) of the Act; and

(C) The payment rates are adequate to assure that recipients have reasonable access, taking into account geographic location and reasonable travel time, to inpatient hospital services of adequate quality.

(iii) With respect to nursing facility services—

(A) Except for preadmission screening for individuals with mental illness and mental retardation under § 483.20(f) of this Chapter, the methods and standards used to determine payment rates take into account the costs of complying with the requirements of part 483 subpart B of this chapter;

(B) The methods and standards used to determine payment rates provide for an appropriate reduction to take into account the lower costs (if any) of the facility for nursing care under a waiver of the requirement in § 483.30(c) of this Chapter to provide licensed nurses on a 24-hour basis;

(C) The State establishes procedures under which the data and methodology used in establishing payment rates are made available to the public.

(2) *Upper payment limits.* The agency's proposed payment rate will not exceed the upper payment limits as specified in § 447.272.

(c) *Changes in ownership of hospitals.* In determining payment when there has been a sale or transfer of the assets of a hospital, the State's methods and standards must provide that payment rates can reasonably be expected not to increase in the aggregate solely as a result of changes of ownership, more than the payments would increase under Medicare under §§ 413.130, 413.134, 413.153, and 413.157 of this chapter, insofar as these sections affect payments for depreciation, interest on capital indebtedness, return on equity capital (if applicable), acquisition costs for which payments were previously made to prior owners, and the recapture of depreciation.

(d) *Changes in ownership of NFs and ICFs/MR.* In determining payment when there has been a sale or transfer of assets of an NF or ICF/MR, the State's methods and standards must provide the following depending upon the date of the transfer.

(1) For transfers on or after July 18, 1984 but before October 1, 1985, the State's methods and standards must provide that payment rates can reasonably be expected not to increase in the aggregate, solely as the result of a change in ownership, more than payments would increase under Medicare under §§ 413.130, 413.134, 413.153 and 413.157 of this chapter, insofar as these sections affect payment for depreciation, interest on capital indebtedness, return on equity capital (if applicable), acquisition costs for which payments were previously made to prior owners, and the recapture of depreciation.

(2) For transfers on or after October 1, 1985, the State's methods and standards must provide that the valuation of capital assets for purposes of determining payment rates for NFs and ICFs/MR is not to increase (as measured from the date of acquisition by the seller to the date of the change of ownership) solely as a result of a change of ownership, by more than the lesser of—

(i) One-half of the percentage increase (as measured from the date of acquisition by the seller to the date of the change of ownership, or, if necessary, as extrapolated retrospectively by the Secretary) in the Dodge construction index applied in the aggregate with respect to those facilities that have undergone a change of ownership during the fiscal year; or

(ii) One-half of the percentage increase (as measured from the date of acquisition by the seller to the date of the change of ownership) in the Consumer Price Index for All Urban Consumers (CPI-U) (United States city average) applied in the aggregate with respect to those facilities that have undergone a change of ownership during the fiscal year.

(e) *Provider appeals.* The Medicaid agency must provide an appeals or exception procedure that allows individual providers an opportunity to submit additional evidence and receive prompt administrative review, with respect to such issues as the agency determines appropriate, of payment rates.

(f) *Uniform cost reporting.* The Medicaid agency must provide for the filing of uniform cost reports by each participating provider.

(g) *Audit requirements.* The Medicaid agency must provide for periodic audits of the financial and statistical records of participating providers.

(h) *Public notice.* The Medicaid agency must provide that it has complied with the public notice requirements in § 447.205 of this part when it is proposing significant changes to its methods or standards for setting payment rates for inpatient hospital or LTC facility services.

(i) *Rates paid.* The Medicaid agency must pay for inpatient hospital and long term care services using rates determined in accordance with methods and standards specified in an approved State plan.

[48 FR 56057, Dec. 19, 1983, as amended at 52 FR 28147, July 28, 1987; 54 FR 5359, Feb. 2, 1989; 57 FR 43921, Sept. 23, 1992]

§ 447.255 Related information.

The Medicaid agency must submit, with the assurances described in § 447.253(a), the following information:

(a) The amount of the estimated average proposed payment rate for each type of provider (hospital, ICF/MR, or nursing facility), and the amount by which that estimated average rate increased or decreased relative to the average payment rate in effect for each type or provider for the immediately preceding rate period;

(b) An estimate of the short-term and, to the extent feasible, long-term effect the change in the estimated average rate will have on—

(1) The availability of services on a Statewide and geographic area basis;

(2) The type of care furnished;

(3) The extent of provider participation; and

(4) The degree to which costs are covered in hospitals that serve a disproportionate number of low income patients with special needs.

[48 FR 56058, Dec. 19, 1983, as amended at 54 FR 5359, Feb. 2, 1989; 56 FR 48867, Sept. 26, 1991; 57 FR 43924, Sept. 23, 1992; 57 FR 46431, Oct. 8, 1992]

§ 447.256 Procedures for CMS action on assurances and State plan amendments.

(a) *Criteria for approval.* (1) CMS approval action on State plans and State plan amendments, is taken in accordance with subpart B of part 430 of this chapter and sections 1116, 1902(b) and 1915(f) of the Act.

(2) In the case of State plan and plan amendment changes in payment methods and standards, CMS bases its approval on the acceptability of the Medicaid agency's assurances that the requirements of § 447.253 have been met, and the State's compliance with the other requirements of this subpart.

(b) *Time limit.* CMS will send a notice to the agency of its determination as to whether the assurances regarding a State plan amendment are acceptable within 90 days of the date CMS receives the assurances described in § 447.253, and the related information described in § 447.255 of this subpart. If CMS does not send a notice to the agency of its determination within this time limit and the provisions in paragraph (a) of this section are met, the assurances and/or the State plan amendment will be deemed accepted and approved.

(c) *Effective date.* A State plan amendment that is approved will become effective not earlier than the first day of the calendar quarter in which an approvable amendment is submitted in accordance with § 430.20 of this chapter and 447.253.

[48 FR 56058, Dec. 19, 1983, as amended at 52 FR 28147, July 28, 1987]

Federal Financial Participation

§ 447.257 FFP: Conditions relating to institutional reimbursement.

FFP is not available for a State's expenditures for hospital inpatient or long-term care facility services that are in excess of the amounts allowable under this subpart.

[52 FR 28147, July 28, 1987]

UPPER LIMITS

§ 447.271 Upper limits based on customary charges.

(a) The agency may not pay a provider more for inpatient hospital services under Medicaid than the provider's customary charges to the general public for the services.

(b) [Reserved]

[72 FR 29834, May 29, 2007]

§ 447.272 Inpatient services: Application of upper payment limits.

(a) *Scope.* This section applies to rates set by the agency to pay for inpatient services furnished by hospitals, nursing facilities, and ICFs/MR within one of the following categories:

(1) State government operated facilities (that is, all facilities that are operated by the State) as defined at § 433.50(a) of this chapter.

(2) Non-State government operated facilities (that is, all governmentally operated facilities that are not operated by the State) as defined at § 433.50(a) of this chapter.

(3) Privately operated facilities, that is, all facilities that are not operated by a unit of government as defined at § 433.50(a) of this chapter.

(b) *General rules.* (1) For privately operated facilities, upper payment limit refers to a reasonable estimate of the amount that would be paid for the services furnished by the group of facilities under Medicare payment principles in subchapter B of this chapter.

(2) For State government operated facilities and for non-State government operated facilities, upper payment limit refers to the individual health care provider's Medicaid cost as defined at § 447.206.

(3) Except as provided in paragraph (c) of this section, aggregate Medicaid payments to the group of privately operated facilities described in paragraph (a) of this section may not exceed the upper payment limit described in paragraph (b)(1) of this section.

(4) Except as provided in paragraph (c) of this section, Medicaid payments to State government operated facilities and non-State government operated facilities must not exceed the individual health care provider's Medicaid cost as documented in accordance with § 447.206.

(c) *Exceptions—(1) Indian Health Services and tribal facilities.* The limitation in paragraph (b) of this section does not apply to Indian Health Services facilities and tribal facilities that are funded through the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638).

(2) *Disproportionate share hospitals.* The limitation in paragraph (b) of this section does not apply to payment adjustments made under section 1923 of the Act that are made under a State plan to hospitals found to serve a disproportionate number of low-income patients with special needs as provided in section 1902(a)(13)(A)(iv) of the Act. Disproportionate share hospital (DSH) payments are subject to the following limits:

(i) The aggregate DSH limit using the Federal share of the DSH limit under section 1923(f) of the Act.

(ii) The hospital-specific DSH limit in section 1923(g) of the Act.

(iii) The aggregate DSH limit for institutions for mental disease (IMDs) under section 1923(h) of the Act.

(3) The limitation in paragraph (b) of this section does not apply to payments authorized by Sections 701(d) and 705 of the Benefits Improvement Protection Act of 2000 (BIPA).

(d) *Compliance dates.* Except as permitted under paragraph (e) of this section, a State must comply with the upper payment limit described in paragraph (b) of this section by one of the following dates:

(1) For State government operated and non-State government operated hospitals, nursing facilities and ICFs/MR '' Medicaid State plan rate year 2008.

(2) For all other facilities—March 13, 2001.

(e) *Transition periods*—(1) *Definitions.* For purposes of this paragraph, the following definitions apply:

(i) *Transition period* refers to the period of time beginning March 13, 2001 through the end of one of the schedules permitted under paragraph (e)(2)(ii) of this section.

(ii) *UPL* stands for the upper payment limit described in paragraph

(b)(1) of this section for the referenced year.

(iii) *X* stands for the payments to a specific group of providers described in paragraphs (a)(2) and (a)(3) of this section in State FY 2000 that exceeded the amount that would have been under the upper payment limit described in paragraph (b) of this section if that limit had been applied to that year.

(2) *General rules.* (i) The amount that a State's payment exceeded the upper payment limit described in paragraph (b) of this section must not increase.

(ii) A State with an approved State plan amendment payment provision effective on one of the following dates and that makes payments that exceed the upper payment limit described in paragraph (b) of this section to providers described in paragraphs (a)(2) and (a)(3) of this section may follow the respective transition schedule:

(A) For State plan provisions that are effective after September 30, 1999 and were approved before January 22, 2001, payments may exceed the upper payment limit in paragraph (b) of this section until September 30, 2002.

(B) For approved plan provisions that are effective after October 1, 1992 and before October 1, 1999, payments during the transition period may not exceed the following—

(*1*) For State FY 2003: State FY 2003 UPL + .75X.

(*2*) For State FY 2004: State FY 2004 UPL + .50X.

(*3*) For State FY 2005: State FY 2005 UPL + .25X.

(*4*) For State FY 2006; State FY 2006 UPL.

(C) For approved plan provisions that are effective on or before October 1, 1992, payments during the transition period may not exceed the following:

(*1*) For State FY 2004: State FY 2004 UPL + .85X.

(*2*) For State FY 2005: State FY 2005 UPL + .70X.

(*3*) For State FY 2006: State FY 2006 UPL + .55X.

(*4*) For State FY 2007: State FY 2007 UPL + .40X.

(*5*) For State FY 2008: State FY 2008 UPL + .25X.

(*6*) For the portion of State FY 2009 before October 1, 2008: State FY 2009 UPL + .10X.

(*7*) Beginning October 1, 2008: UPL described in paragraph (b) of this section.

(D) For State plan provisions that were effective after September 30, 1999, submitted to CMS before March 13, 2001, and approved by CMS after January 21, 2001, payments may exceed the limit in paragraph (b) of this section until the later of November 5, 2001, or 1 year from the approved effective date of the State plan provision.

(iii) When State FY 2003 begins after September 30, 2002, the reduction schedule in paragraphs (e)(2)(ii)(C)(*1*) through (e)(2)(ii)(C)(*7*) will begin on State FY 2003.

(iv) If a State meets the criteria in paragraph (e)(2)(ii) of this section and its State plan amendment expires before the end of the applicable transition period, the State may continue making payments that exceed the UPL described in paragraph (b) of this section in accordance with the applicable transition schedule described in paragraph (e)(2)(ii) of this section.

(v) A State with an approved State plan amendment payment provision that makes payments up to 150 percent of the UPL described in paragraph (b)(1) of this section to providers described in paragraph (a)(2) of this section does not qualify for a transition period.

(f) *Reporting requirements for payments during the transition periods.* States that are eligible for a transition period described in paragraph (e) of this section, and that make payments that exceed the upper payment limit under paragraph (b)(1) of this section, must report annually the following information to CMS:

(1) The total Medicaid payments made to each facility for services furnished during the entire State fiscal year.

(2) A reasonable estimate of the amount that would be paid for the services furnished by the facility under Medicare payment principles.

[66 FR 3175, Jan. 12, 2001, as amended at 66 FR 46399, Sept. 5, 2001; 67 FR 2610, Jan. 18, 2002; 72 FR 29834, May 29, 2007]

SWING-BED HOSPITALS

§ 447.280 Hospital providers of NF services (swing-bed hospitals).

(a) *General rule.* If the State plan provides for NF services furnished by a swing-bed hospital, as specified in §§ 440.40(a) and 440.150(f) of this chapter, the methods and standards used to determine payment rates for routine NF services must—

(1) Provide for payment at the average rate per patient day paid to NFs, as applicable, for routine services furnished during the previous calendar year; or

(2) Meet the State plan and payment requirements described in this subpart, as applicable.

(b) *Application of the rule.* The payment methodology used by a State to set payment rates for routine NF services must apply to all swing-bed hospitals in the State.

[59 FR 56237, Nov. 10, 1994]

Subpart D [Reserved]

Subpart E—Payment Adjustments for Hospitals That Serve a Disproportionate Number of Low-Income Patients

SOURCE: 57 FR 55143, Nov. 24, 1992, unless otherwise noted.

§ 447.296 Limitations on aggregate payments for disproportionate share hospitals for the period January 1, 1992 through September 30, 1992.

(a) The provisions of this section apply to the 50 States and the District of Columbia, but not to any State whose entire Medicaid program is operated under a waiver granted under section 1115 of the Act.

(b) For the period January 1, 1992 through September 30, 1992, FFP is available for aggregate payments to hospitals that serve a disproprotionate number of low-income patients with special needs only if the payments are made in accordance with sections 1902(a)(13)(A) and 1923 of the Act, and with one of the following:

(1) An approved State plan in effect as of September 30, 1991.

(2) A State plan amendment submitted to CMS by September 30, 1991.

(3) A State plan amendment, or modification thereof, submitted to CMS between October 1, 1991 and November 26, 1991, if the amendment, or modification thereof, was intended to limit the State's definition of disproportionate share hospitals to those hospitals with Medicaid inpatient utilization rates or low-income utilization rates (as defined in section 1923 (b) of the Act) at or above the statewide arithmetic mean.

(4) A methodology for disproportionate share hospital payments that was established and in effect as of September 30, 1991, or in accordance with a State law enacted or State regulation adopted as of September 30, 1991.

(5) A State plan amendment submitted to CMS by September 30, 1992 that increases aggregate disproportionate share hospitals payments in order to meet the minimum payment adjustments required by section 1923(c)(1) of the Act. The minimum payment adjustment is the amount required by the Medicare methodology described in section 1923(c)(1) of the Act for those hospitals that satisfy the minimum Federal definition of a disproportionate share hospital in section 1923(b) of the Act.

(6) A State plan amendment submitted to CMS by September 30, 1992 that provides for a redistribution of disproportionate share hospital payments within the State without raising total payments compared to the previously approved State plan. CMS will approve the amendment only if the State submits written documentation that demonstrates to CMS that the aggregate payments that will be made after the redistribution are no greater than those payments made before the redistribution.

(7) A State plan amendment submitted to CMS by September 30, 1992 that provides for a reduction in disproportionate share hospital payments.

§ 447.297 Limitations on aggregate payments for disproportionate share hospitals beginning October 1, 1992.

(a) *Applicability.* The provisions of this section apply to the 50 States and

the District of Columbia, but not to any State whose entire Medicaid program is operated under a waiver granted under section 1115 of the Act.

(b) *National payment target.* The national payment target for disproportionate share hospital (DSH) payments for any Federal fiscal year is equal to 12 percent of the total medical assistance expenditures that will be made during the Federal fiscal year under State plans, excluding administrative costs. A preliminary national expenditure target will be published by CMS prior to October 1 of each year. This preliminary national expenditure target will be superseded by a final national expenditure target published by April 1 of each Federal fiscal year, as specified in paragraph (d) of this section.

(c) *State disproportionate share hospital allotments.* Prior to October 1 of each Federal fiscal year, CMS will publish in the FEDERAL REGISTER preliminary State DSH allotments for each State. These preliminary State DSH allotments will be determined using the most current applicable actual and estimated State expenditure information as reported to CMS and adjusted by CMS as may be necessary using the methodology described in §447.298. CMS will publish final State DSH allotments by April 1 of each Federal fiscal year, as described in paragraph (d) of this section.

(d) *Final national disproportionate share hospitals expenditure target and State disproportionate share hospitals allotments.*

(1) CMS will revise the preliminary national expenditure target and the preliminary State DSH allotments by April 1 of each Federal fiscal year. The final national DSH expenditure target and State DSH allotments will be based on the most current applicable actual and estimated expenditure information reported to CMS and adjusted by CMS as may be necessary immediately prior to the April 1 publication date. The final national expenditure target and State DSH allotments will not be recalculated for that Federal fiscal year based upon any subsequent actual or estimated expenditure information reported to CMS.

(2) If CMS determines that at any time a State has exceeded its final DSH allotment for a Federal fiscal year, FFP attributable to the excess DSH expenditures will be disallowed.

(3) If a State's actual DSH expenditures applicable to a Federal fiscal year are less than its final State DSH allotment for that Federal fiscal year, the State is permitted, to the extent allowed by its approved State plan, to make additional DSH expenditures applicable to that Federal fiscal year up to the amount of its final DSH allotment for that Federal fiscal year.

(e) *Publication of limits.* (1) Before the beginning of each Federal fiscal year, CMS will publish in the FEDERAL REGISTER—

(i) A preliminary national DSH expenditure target for the Federal fiscal year; and

(ii) A preliminary DSH allotment for each State for the Federal fiscal year.

(2) The final national DSH expenditure target and State DSH allotments will be published in the FEDERAL REGISTER by April 1 of each Federal fiscal year.

[57 FR 55143, Nov. 24, 1992, as amended at 58 FR 43182, Aug. 13, 1993]

§447.298 State disproportionate share hospital allotments.

(a) *Calculation of State's base allotment for Federal fiscal year 1993.* (1) For Federal fiscal year 1993, CMS will calculate for each State a DSH allotment, using the State's ''base allotment.'' The State's base allotment is the greater of:

(i) The total amount of the State's projected DSH payments for Federal fiscal year 1992 under the State plan applicable to Federal fiscal year 1992, calculated in accordance with paragraph (a)(2) of this section; or

(ii) $1,000,000.

(2) In calculating the State's DSH payments applicable to Federal fiscal year 1992, CMS will derive amounts from payments applicable to the period of October 1, 1991, through September 30, 1992, under State plans or plan amendments that meet the requirements specified in §447.296(b). The calculation will not include—

(i) DSH payment adjustments made by the State applicable to the period

October 1, 1991 through December 31, 1991 under State plans or plan amendments that do not meet the criteria described in § 447.296; and

(ii) Retroactive DSH payments made in 1992 that are not applicable to Federal fiscal year 1992.

(3) CMS will calculate a percentage for each State by dividing the DSH base allotment by the total unadjusted medical assistance expenditures, excluding administrative costs, made during Federal fiscal year 1992. On the basis of this percentage, CMS will classify each State as a ''high-DSH'' or ''low-DSH'' State.

(i) If the State's base allotment exceeded 12 percent of its total unadjusted medical assistance expenditures made under the State plan in Federal fiscal year 1992, CMS will classify the State as a ''high-DSH'' State.

(ii) If the State's base allotment was 12 percent or less of its total unadjusted medical assistance expenditures made under the State plan in Federal fiscal year 1992, CMS will classify the State as a ''low-DSH'' State.

(b) *State disproportionate share hospital allotments for Federal fiscal year 1993.* (1) For Federal fiscal year 1993, CMS will calculate a DSH allotment for each low-DSH State that equals the State's base allotment described under paragraph (a) of this section, increased by State growth, as specified in paragraph (d) of this section.

(2) For high-DSH States, the dollar amount of DSH payments in Federal fiscal year 1993 may not exceed the dollar amount of DSH payments applicable to Federal fiscal year 1992 (that is, the State base allotment).

(c) *State disproportionate share hospital allotment for Federal fiscal years 1994 and after.* For Federal fiscal years 1994 and after—

(1) For low-DSH States, CMS will calculate the DSH allotment for each Federal fiscal year by increasing the prior year's State DSHs allotment by—

(i) State growth, as specified in paragraph (d) of this section; and

(ii) A supplemental amount, if applicable, as described in paragraph (e) of this section.

(2) For high-DSH States, the dollar amount of DSH payments applicable to any Federal fiscal year may not exceed the dollar amount of payments applicable to Federal fiscal year 1992 (that is, the State base allotment). This payment limitation will apply until the Federal fiscal year in which the State's DSH payments applicable to that Federal fiscal year, expressed as a percentage of the State's total unadjusted medical assistance expenditures in that Federal fiscal year, equal 12 percent or less. When a high-DSH State's percentage equals 12 percent or less, the State will be reclassified as a low-DSH State.

(d) *State growth.* (1) The State growth for a State in a Federal fiscal year is equal to the product of—

(i) The growth factor that is CMS's projected percentage increase in the State's total unadjusted medical assistance expenditures (including administrative costs) relative to the corresponding amount in the previous year; and

(ii) The State's prior year DSH allotment.

(2) If the growth factor is zero or is negative, the State growth is zero.

(3) If a low-DSH State experiences a level of negative growth to the extent that its previous Federal fiscal year's DSH allotment would be more than 12 percent of its current Federal fiscal year's total unadjusted medical assistance expenditures (excluding administrative costs), the low-DSH State's previous year's DSH allotment will be reduced to the extent necessary to maintain the individual low-DSH State's 12-percent limit and that amount will become the low-DSH State's DSH allotment for the current Federal fiscal year. In no Federal fiscal year will a low-DSH State's DSH allotment be allowed to exceed its individual State 12-percent limit.

(e) *Supplemental amount available for low-DSH States.*

(1) A supplemental amount is the State's share of a pool of money (referred to as a redistribution pool).

(2) CMS will calculate the redistribution pool for the appropriate Federal fiscal year by subtracting from the projected national DSH expenditure target the following:

(i) The total of the State DSH base allotments for all high-DSH States;

(ii) The total of the previous year's State DSH allotments for all low-DSH States;

(iii) The State growth amount for all low-DSH States; and

(iv) The total amount of additional DSH payment adjustments made in order to meet the minimum payment adjustments required under section 1923(c)(l) of the Act, which are made in accordance with §447.296(b)(5).

(3) CMS will determine the percent of the redistribution pool for each low-DSH State on the basis of each State's relative share of the total unadjusted medical assistance expenditures for the Federal fiscal year compared to the total unadjusted medical assistance expenditures for the Federal fiscal year projected to be made by all low-DSH States. The percent of the redistribution pool that each State will receive is equal to the State's total unadjusted medical assistance expenditures divided by the total unadjusted medical assistance expenditures for all low-DSH States.

(4) CMS will not provide any low-DSH State a supplemental amount that would result in the State's total DSH allotment exceeding 12 percent of its projected total unadjusted medical assistance expenditures. CMS will reallocate any supplemental amounts not allocated to States because of this 12-percent limitation to other low-DSH States in accordance with the percentage determined in paragraph (e)(3) of this section.

(5) CMS will not reallocate to low-DSH States the difference between any State's actual DSH expenditures applicable to a Federal fiscal year and its State DSH allotment applicable to that Federal fiscal year. Thus, any unspent DSH allotment may not be reallocated.

(f) *Special provision.* Any increases in a State's aggregate disproportionate payments, that are made to meet the minimum payment requirements specified in §447.296(b)(5), may exceed the State base allotment to the extent such increases are made to satisfy the minimum payment requirement. In such cases, CMS will adjust the State's base allotment in the subsequent Federal fiscal year to include the increased minimum payments.

[57 FR 55143, Nov. 24, 1992, as amended at 58 FR 43182, Aug. 13, 1993]

§447.299 Reporting requirements.

(a) Beginning with the first quarter of Federal fiscal year 1993, each State must submit to CMS the quarterly aggregate amount of its disproportionate share hospital payments made to each individual public and private provider or facility. States' reports must present a complete, accurate, and full disclosure of all of their DSH programs and expenditures.

(b) Each State must report the aggregate information specified under paragraph (a) of this section on a quarterly basis in accordance with procedures established by CMS.

(c) Each State must maintain, in readily reviewable form, supporting documentation that provides a detailed description of each DSH program, the legal basis of each DSH program, and the amount of DSH payments made to each individual public and private provider or facility each quarter. This information must be made available to Federal reviewers upon request.

(d) If a State fails to comply with the reporting requirements contained in this section, future grant awards will be reduced by the amount of FFP CMS estimates is attributable to the expenditures made to the disproportionate share hospitals as to which the State has not reported properly, until such time as the State complies with the reporting requirements. Deferrals and/or disallowances of equivalent amounts may also be imposed with respect to quarters for which the State has failed to report properly. Unless otherwise prohibited by law, FFP for those expenditures will be released when the State complies with all reporting requirements.

Subpart F—Payment Methods for Other Institutional and Non-institutional Services

SOURCE: 43 FR 45253, Sept. 29, 1978, unless otherwise noted. Redesignated at 46 FR 47973, Sept. 30, 1981, and further redesignated at 58 FR 6095, Jan. 26, 1993.

§ 447.300 Basis and purpose.

In this subpart, § 447.302 through § 447.325 and § 447.361 implement section 1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy and quality of care. Section 447.371 implements section 1902(a)(15) of the Act, which requires that the State plan provide for payment for rural health clinic services in accordance with regulations prescribed by the Secretary.

[72 FR 39239, July 17, 2007]

§ 447.302 State plan requirements.

A State plan must provide that the requirements of this subpart are met.

[46 FR 48560, Oct. 1, 1981]

§ 447.304 Adherence to upper limits; FFP.

(a) The Medicaid agency must not pay more than the upper limits described in this subpart.

(b) In the case of payments made under the plan for deductibles and coinsurance payable on an assigned Medicare claim for noninstitutional services, those payments may be made only up to the reasonable charge under Medicare.

(c) FFP is not available for a State's expenditures for services that are in excess of the amounts allowable under this subpart.

NOTE: The Secretary may waive any limitation on reimbursement imposed by subpart F of this part for experiments conducted under section 402 of Pub. L. 90–428, Incentives for Economy Experimentation, as amended by section 222(b) of Pub. L. 92–603, and under section 222(a) of Pub. L. 92–603.

[46 FR 48560, Oct. 1, 1981; 46 FR 54744, Nov. 4, 1981, as amended at 66 FR 3176, Jan. 12, 2001]

OUTPATIENT HOSPITAL AND CLINIC SERVICES

§ 447.321 Outpatient hospital and clinic services: Application of upper payment limits.

(a) *Scope.* This section applies to rates set by the agency to pay for outpatient services furnished by hospitals and clinics within one of the following categories:

(1) State government operated facilities (that is, all facilities that are operated by the State) as defined at § 433.50(a) of this chapter.

(2) Non-State government operated facilities (that is, all governmentally operated facilities that are not operated by the State) as defined at § 433.50(a) of this chapter.

(3) Privately operated facilities that is, all facilities that are not operated by a unit of government as defined at § 433.50(a) of this chapter.

(b) *General rules.* (1) For privately operated facilities, upper payment limit refers to a reasonable estimate of the amount that would be paid for the services furnished by the group of facilities under Medicare payment principles in subchapter B of this chapter.

(2) For State government operated facilities and for non-State government operated facilities, upper payment limit refers to the individual health care provider's Medicaid cost as defined at § 447.206.

(3) Except as provided in paragraph (c) of this section, aggregate Medicaid payments to the group of privately operated facilities within one of the categories described in paragraph (a) of this section may not exceed the upper payment limit described in paragraph (b)(1) of this section.

(4) Except as provided in paragraph (c) of this section, Medicaid payments to State government operated facilities and non-State government operated facilities must not exceed the individual health care provider's Medicaid cost as documented in accordance with § 447.206.

(c) *Exceptions—(1) Indian Health Services and tribal facilities.* The limitation in paragraph (b) of this section does not apply to Indian Health Services facilities and tribal facilities that are funded through the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638).

(2) *Disproportionate share hospitals.* The limitation in paragraph (b) of this section does not apply to payment adjustments made under section 1923 of the Act that are made under a State plan to hospitals found to serve a disproportionate number of low-income patients with special needs as provided in section 1902(a)(13)(A)(iv) of the Act. Disproportionate share hospital (DSH)

payments are subject to the following limits:

(i) The aggregate DSH limit using the Federal share of the DSH limit under section 1923(f) of the Act.

(ii) The hospital-specific DSH limit in section 1923(g) of the Act.

(iii) The aggregate DSH limit for institutions for mental disease (IMDs) under section 1923(h) of the Act.

(3) The limitation in paragraph (b) of this section does not apply to payments authorized by Sections 701(d) and 705 of the Benefits Improvement Protection Act of 2000 (BIPA).

(d) *Compliance dates.* Except as permitted under paragraph (e) of this section, a State must comply with the upper payment limit described in paragraph (b) of this section by one of the following dates:

(1) For State government operated and non-State government operated hospitals—Medicaid State plan rate year 2008.

(2) For State government operated and non-State government operated clinics—Medicaid State plan rate year 2009.

(3) For all other facilities—March 13, 2001.

(e) *Transition periods*—(1) *Definitions.* For purposes of this paragraph, the following definitions apply:

(i) *Transition period* refers to the period of time beginning March 13, 2001 through the end of one of the schedules permitted under paragraph (e)(2)(ii) of this section.

(ii) *UPL* stands for the upper payment limit described in paragraph (b)(1) of this section for the referenced year.

(iii) *X* stands for the payments to a specific group of providers described in paragraph (a) of this section in State FY 2000 that exceeded the amount that would have been under the upper payment limit described in paragraph (b) of this section if that limit had been applied to that year.

(2) *General rules.* (i) The amount that a State's payment exceeded the upper payment limit described in paragraph (b) of this section must not increase.

(ii) A State with an approved State plan amendment payment provision effective on one of the following dates and that makes payments that exceed the upper payment limit described in paragraph (b) of this section to providers described in paragraph (a) of this section may follow the respective transition schedule:

(A) For State plan provisions that are effective after September 30, 1999 and were approved before January 22, 2001, payments may exceed the upper payment limit in paragraph (b) of this section until September 30, 2002.

(B) *For approved plan provisions that are effective after October 1, 1992 and before October 1, 1999, payments during the transition period may not exceed the following—*

(*1*) For State FY 2003: State FY 2003 UPL + .75X.

(*2*) For State FY 2004: State FY 2004 UPL + .50X.

(*3*) For State FY 2005: State FY 2005 UPL + .25X.

(*4*) For State FY 2006; State FY 2006 UPL.

(C) *For approved plan provisions that are effective on or before October 1, 1992, payments during the transition period may not exceed the following:*

(*1*) For State FY 2004: State FY 2004 UPL + .85X.

(*2*) For State FY 2005: State FY 2005 UPL + .70X.

(*3*) For State FY 2006: State FY 2006 UPL + .55X.

(*4*) For State FY 2007: State FY 2007 UPL + .40X.

(*5*) For State FY 2008: State FY 2008 UPL + .25X.

(*6*) For the portion of State FY 2009 before October 1, 2008: State FY 2009 UPL + .10X.

(*7*) Beginning October 1, 2008: UPL described in paragraph (b) of this section.

(D) For State plan provisions that were effective after September 30, 1999, submitted to CMS before March 13, 2001, and approved by CMS after January 21, 2001, payments may exceed the limit in paragraph (b) of this section until the later of November 5, 2001, or 1 year from the approved effective date of the State plan provision.

(iii) When State FY 2003 begins after September 30, 2002, the reduction schedule in paragraphs (e)(2)(ii)(C)(1) through (e)(2)(ii)(C)(7) will begin on State FY 2003.

(iv) If a State meets the criteria in paragraph (e)(2)(ii) of this section and

its State plan amendment expires before the end of the applicable transition period, the State may continue making payments that exceed the UPL described in paragraph (b) of this section in accordance with the applicable transition schedule described in paragraph (e)(2)(ii) of this section.

(v) A State with an approved State plan amendment payment provision that makes payments up to 150 percent of the UPL described in paragraph (b)(1) of this section to providers described in paragraph (a)(2) of this section does not qualify for a transition period.

(f) *Reporting requirements for payments during the transition periods.* States that are eligible for a transition period described in paragraph (e) of this section, and that make payments that exceed the limit under paragraph (b)(1) of this section, must report annually the following information to CMS:

(1) The total Medicaid payments made to each facility for services furnished during the entire State fiscal year.

(2) A reasonable estimate of the amount that would be paid for the services furnished by the facility under Medicare payment principles.

[66 FR 3176, Jan. 12, 2001, as amended at 66 FR 46399, Sept. 5, 2001; 67 FR 2611, Jan. 18, 2002; 72 FR 29835, May 29, 2007]

OTHER INPATIENT AND OUTPATIENT FACILITIES

§ 447.325 Other inpatient and outpatient facility services: Upper limits of payment.

The agency may pay the customary charges of the provider but must not pay more than the prevailing charges in the locality for comparable services under comparable circumstances.

§ 447.342 [Reserved]

PREPAID CAPITATION PLANS

§ 447.362 Upper limits of payment: Nonrisk contract.

Under a nonrisk contract, Medicaid payments to the contractor may not exceed—

(a) What Medicaid would have paid, on a fee-for-service basis, for the services actually furnished to recipients: plus

(b) The net savings of administrative costs the Medicaid agency achieves by contracting with the plan instead of purchasing the services on a fee-for-service basis.

[48 FR 54025, Nov. 30, 1983]

RURAL HEALTH CLINIC SERVICES

§ 447.371 Services furnished by rural health clinics.

The agency must pay for rural health clinic services, as defined in § 440.20(b) of this subchapter, and for other ambulatory services furnished by a rural health clinic, as defined in § 440.20(c) of this subchapter, as follows:

(a) For provider clinics, the agency must pay the reasonable cost of rural health clinic services and other ambulatory services on the basis of the cost reimbursement principles in part 413 of this chapter. For purposes of this section, a provider clinic is an integral part of a hospital, skilled nursing facility, or home health agency that is participating in Medicare and is licensed, governed, and supervised with other departments of the facility.

(b) For clinics other than provider clinics that do not offer any ambulatory services other than rural health clinic services, the agency must pay for rural health clinic services at the reasonable cost rate per visit determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter.

(c) For clinics other than provider clinics that do offer ambulatory services other than rural health clinic services, the agency must pay for the other ambulatory services by one of the following methods:

(1) The agency may pay for other ambulatory services and rural health clinic services at a single rate per visit that is based on the cost of all services furnished by the clinic. The rate must be determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter.

(2) The agency may pay for other ambulatory services at a rate set for each service by the agency. The rate must not exceed the upper limits in this subpart. The agency must pay for rural health clinic services at the Medicare

reimbursement rate per visit, as specified in § 405.2426 of this chapter.

(3) The agency may pay for dental services at a rate per visit that is based on the cost of dental services furnished by the clinic. The rate must be determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter. The agency must pay for ambulatory services other than dental services under paragraph (c) (1) or (2) of this section.

(d) For purposes of paragraph (c) (1) and (3) of this section, ''visit'' means a face-to-face encounter between a clinic patient and any health professional whose services are reimbursed under the State plan. Encounters with more than one health professional, and multiple encounters with the same health professional, that take place on the same day and at a single location constitute a single visit, except when the patient, after the first encounter, suffers illness or injury requiring additional diagnosis or treatment.

[43 FR 45253, Sept. 29, 1978, as amended at 51 FR 34833, Sept. 30, 1986]

Subparts G–H [Reserved]

Subpart I—Payment for Drugs

SOURCE: 72 FR 39239, July 17, 2007, unless otherwise noted.

§ 447.500 Basis and purpose.

(a) *Basis.* This subpart—

(1) Interprets those provisions of section 1927 of the Act that set forth requirements for drug manufacturers' calculating and reporting average manufacturer prices (AMPs) and that set upper payment limits for covered outpatient drugs.

(2) Implements section 1903(i)(10) of the Act with regard to the denial of Federal financial participation (FFP) in expenditures for certain physician-administered drugs.

(3) Implements section 1902(a)(54) of the Act with regard to a State plan that provides covered outpatient drugs.

(b) *Purpose.* This subpart specifies certain requirements in the Deficit Reduction Act of 2005 and other requirements pertaining to Medicaid payment for drugs.

§ 447.502 Definitions.

Bona fide service fees mean fees paid by a manufacturer to an entity; that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Brand name drug means a single source or innovator multiple source drug.

Bundled sale means an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. For bundled sales, the discounts are allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement shall be proportionally allocated across all the drugs in the bundle.

Consumer Price Index—Urban (CPI–U) means the index of consumer prices developed and updated by the U.S. Department of Labor. It is the CPI for all urban consumers (U.S. average) for the month before the beginning of the calendar quarter for which the rebate is paid.

Dispensing fee means the fee which—

(1) Is incurred at the point of sale or service and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;

(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient

drug is transferred to a Medicaid recipient. Pharmacy costs include, but are not limited to, reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and

(3) Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

Estimated acquisition cost (EAC) means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.

Innovator multiple source drug means a multiple source drug that was originally marketed under an original new drug application (NDA) approved by the Food and Drug Administration (FDA), including an authorized generic drug. It includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a product license approval (PLA), establishment license approval (ELA) or antibiotic drug approval (ADA).

Lagged price concession means any discount or rebate that is realized after the sale of the drug, but does not include customary prompt pay discounts.

Manufacturer means any entity that possesses legal title to the NDC for a covered drug or biological product and—

(1) Is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

(2) Is engaged in the packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drug products and is not a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(3) With respect to authorized generic products, the term ''manufacturer'' will also include the original holder of the NDA.

(4) With respect to drugs subject to private labeling arrangements, the term ''manufacturer'' will also include the entity that does not possess legal title to the NDC.

Multiple source drug means, with respect to a rebate period, a covered outpatient drug for which there is at least one other drug product which—

(1) Is rated as therapeutically equivalent. For the list of drug products rated as therapeutically equivalent, see the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' which is available at *http://www.fda.gov/cder/orange/default.htm* or can be viewed at the FDA's Freedom of Information Public Reading Room at 5600 Fishers Lane, rm. 12A–30, Rockville, MD 20857;

(2) Is pharmaceutically equivalent and bioequivalent, as determined by the FDA; and

(3) Is sold or marketed in the United States during the rebate period.

National drug code (NDC) means the 11-digit numerical code maintained by the FDA that indicates the labeler, product, and package size, unless otherwise specified in this part as being without respect to package size (that is, the 9-digit numerical code).

National rebate agreement means the rebate agreement developed by CMS and entered into by CMS on behalf of the Secretary or his designee and a manufacturer to implement section 1927 of the Act.

Nominal price means a price that is less than ten percent of the AMP in the same quarter for which the AMP is computed.

Noninnovator multiple source drug means (1) a multiple source drug that is not an innovator multiple source drug or a single source drug, (2) a multiple source drug that is marketed

under an abbreviated NDA or an abbreviated antibiotic drug application, or (3) a drug that entered the market before 1962 that was not originally marketed under an original NDA.

Rebate period means a calendar quarter.

Single source drug means a covered outpatient drug that is produced or distributed under an original NDA approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It also includes a covered outpatient drug approved under a biological license application, PLA, ELA, or ADA.

States means the 50 States and the District of Columbia.

§ 447.504 Determination of AMP.

(a) *AMP* means, with respect to a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (FFDCA)) for a calendar quarter, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers. AMP shall be calculated to include all sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation.

(b) *Average unit price* means a manufacturer's quarterly sales included in AMP less all required adjustments divided by the total units sold and included in AMP by the manufacturer in a quarter.

(c) *Customary prompt pay discount* means any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified timeframe and consistent with customary business practices for payment.

(d) *Net sales* means quarterly gross sales revenue less cash discounts allowed, except customary prompt pay discounts extended to wholesalers, and all other price reductions (other than rebates under section 1927 of the Act or price reductions specifically excluded by statute or regulation) which reduce the amount received by the manufacturer.

(e) *Retail pharmacy class of trade* means any independent pharmacy, chain pharmacy, mail order pharmacy, or other outlet that purchases drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public.

(f) *Wholesaler* means any entity (including those entities in the retail pharmacy class of trade) to which the manufacturer sells the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug.

(g) *Sales, rebates, discounts, or other price concessions included in AMP.* Except with respect to those sales identified in paragraph (h) of this section, AMP for covered outpatient drugs shall include the following sales and associated rebates, discounts, or other price concessions—

(1) Sales to wholesalers, except for those sales that can be identified with adequate documentation as being subsequently sold to any of the excluded entities as specified in paragraph (h) of this section;

(2) Sales to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser's NDC, including private labeling agreements;

(3) Direct and indirect sales to hospitals, where the drug is used in the outpatient pharmacy, except those sales that cannot be identified with adequate documentation as being used in the outpatient pharmacy for outpatient use (for example hospital outpatient department, clinic, or affiliated entity);

(4) Sales at nominal prices to any entity except a covered entity described in section 340B(a)(4) of the Public Health Service Act (PHSA), an intermediate care facility for the mentally retarded (ICF/MR) providing services as set forth in § 440.150 of this chapter,

or a State-owned or operated nursing facility providing services as set forth in § 440.155 of this chapter;

(5) Sales to retail pharmacies including discounts or other price concessions that adjust prices either directly or indirectly on sales of drugs to the retail pharmacy class of trade;

(6) Sales including discounts, rebates, or other price concessions provided to pharmacy benefit managers (PBMs) for their mail order pharmacy purchases;

(7) Sales directly to patients;

(8) Sales to outpatient facilities (for example, clinics, surgical centers, ambulatory care centers, dialysis centers, and mental health centers);

(9) Sales to mail order pharmacies;

(10) Sales to home infusion providers;

(11) Sales to specialty pharmacies;

(12) Sales to home health care providers;

(13) Sales to physicians;

(14) Rebates, discounts, or other price concessions (other than rebates under section 1927 of the Act or as otherwise specified in the statute or regulations) associated with sales of drugs provided to the retail pharmacy class of trade; and

(15) Sales of drugs reimbursed by third party payers including the Medicare Part D Program, a Medicare Advantage prescription drug plan (MA–PD), a Qualified Retiree Prescription Drug Plan under section 1860D–22(a)(2) of the Act, State Children's Health Insurance Program (SCHIP), State pharmaceutical assistance programs (SPAPs), health maintenance organizations (HMOs) (including managed care organizations (MCOs)) that do not purchase or take possession of drugs, TRICARE Retail Pharmacy Program (TRRx), and Medicaid Programs that are associated with sales of drugs provided to the retail pharmacy class of trade (except for rebates under section 1927 of the Act or as otherwise specified in the statute or regulations).

(h) *Sales, rebates, discounts, or other price concessions excluded from AMP.* AMP excludes—

(1) Any prices on or after October 1, 1992, to the Indian Health Service (IHS), the Department of Veterans Affairs (DVA), a State home receiving funds under 38 U.S.C. 1741, the Department of Defense (DoD), the Public Health Service (PHS), or a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA);

(2) Any prices charged under the Federal Supply Schedule (FSS) of the General Services Administration (GSA);

(3) Any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(4) Direct and indirect sales to hospitals, where the drug is used in the inpatient setting or in the outpatient pharmacy for outpatient use where the sales cannot be identified with adequate documentation;

(5) Sales to HMOs (including MCOs, and HMO/MCO-operated pharmacies) that purchase or take possession of drugs;

(6) Sales to long-term care facilities, including nursing facility pharmacies, contract pharmacies for the nursing facility where these sales can be identified with adequate documentation, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities;

(7) Sales to hospices (inpatient and outpatient);

(8) Sales to veterinarians;

(9) Sales to prisons;

(10) Sales outside the 50 States and the District of Columbia;

(11) Sales to State, county, and municipal entities;

(12) Sales to patient assistance programs;

(13) Sales to wholesalers where the drug is distributed to the non-retail pharmacy class of trade;

(14) Sales to wholesalers or distributors where the drug is relabeled under the wholesalers' or distributors' NDC number;

(15) Manufacturer coupons redeemed by a consumer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession;

(16) Manufacturer vouchers;

(17) Manufacturer-sponsored drug discount card programs;

(18) Free goods, not contingent upon any purchase requirement;

(19) Bona fide service fees;

(20) Customary prompt pay discounts extended to wholesalers;

(21) Returned or replaced goods when accepted or replaced in good faith;

(22) Discounts, rebates, or other price concessions to PBMs, except for their mail order pharmacy's purchases.

(23) Associated rebates, discounts, or other price concessions to third party payers including the Medicare Part D Program, an MA–PD, Qualified Retiree Prescription Drug Plan under section 1860D–22(a)(2) of the Act, SCHIP, SPAPs, HMOs (including MCOs that do not take possession of drugs) the TRICARE Retail Pharmacy Program, and Medicaid Programs; and

(24) Rebates under the national rebate agreement or a CMS-authorized State supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act.

(i) *Further clarification of AMP calculation.* (1) AMP includes cash discounts except customary prompt pay discounts extended to wholesalers, free goods that are contingent on any purchase requirement, volume discounts, chargebacks, incentives, administrative fees, service fees, distribution fees, (except bona fide service fees), and any other rebates, discounts or other price concessions, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to the retail pharmacy class of trade.

(2) Quarterly AMP is calculated as a weighted average of monthly AMPs in the quarter.

(3) The manufacturer must adjust the AMP for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized.

§ 447.505 Determination of best price.

(a) *Best price* means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including any drug sold under an NDA approved under section 505(c) of the FFDCA), the lowest price available from the manufacturer during the rebate period to any entity in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price shall be calculated to include all sales and associated rebates, discounts and other price concessions provided by the manufacturer to any entity unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation from the rebate calculation.

(b) For purposes of this section, *provider* means a hospital, HMO, including an MCO or entity that treats or provides coverage or services to individuals for illnesses or injuries or provides services or items in the provision of health care.

(c) *Prices included in best price.* Except with respect to those prices identified in paragraph (d) of this section, best price for covered outpatient drugs includes the following prices and associated rebates, discounts, or other price concessions that adjust prices either directly or indirectly—

(1) Prices to wholesalers;

(2) Prices to any retailer, including rebates, discounts or other price concessions that adjust prices either directly or indirectly on sales of drugs;

(3) Prices to providers (for example, hospitals, HMOs/MCOs, physicians, nursing facilities, and home health agencies);

(4) Prices available to non-profit entities;

(5) Prices available to governmental entities within the United States;

(6) Prices of authorized generic drugs, sold by the primary manufacturer in accordance with § 447.506(d) of this subpart;

(7) Prices of sales directly to patients;

(8) Prices available to mail order pharmacies;

(9) Prices available to outpatient clinics;

(10) Prices to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser's NDC, including private labeling agreements; and

(11) Prices to entities that repackage/relabel under the purchaser's NDC, including private labeling agreements, if

that entity also is an HMO or other non-excluded entity.

(d) *Prices excluded from best price.* Best price excludes:

(1) Any prices on or after October 1, 1992, charged to the IHS, the DVA, a State home receiving funds under 38 U.S.C. 1741, the DoD, the PHS, or a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA);

(2) Any prices charged under the FSS of the GSA;

(3) Any prices provided to a designated SPAP;

(4) Any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(5) Any prices charged which are negotiated by a prescription drug plan under Part D of title XVIII, by any MA–PD plan under Part C of such title with respect to covered Part D drugs, or by a Qualified Retiree Prescription Drug Plan (as defined in section 1860D–22(a)(2) of the Act) with respect to such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare;

(6) Rebates under the national rebate agreement or a CMS-authorized supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act;

(7) Prices negotiated under a manufacturer-sponsored drug discount card program;

(8) Manufacturer coupons redeemed by a consumer, agent, pharmacy or another entity acting on behalf of the manufacturer; but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession;

(9) Goods provided free of charge under a manufacturer's patient assistance programs;

(10) Free goods, not contingent upon any purchase requirement;

(11) Nominal prices to certain entities as set forth in § 447.508 of this subpart;

(12) Bona fide service fees; and

(13) PBM rebates, discounts, or other price concessions except their mail order pharmacy's purchases or where such rebates, discounts, or other price concessions are designed to adjust prices at the retail or provider level.

(e) *Further clarification of best price.* (1) Best price shall be net of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, customary prompt pay discounts, chargebacks, returns, incentives, promotional fees, administrative fees, service fees (except bona fide service fees), distribution fees, and any other discounts or price reductions and rebates, other than rebates under section 1927 of the Act, which reduce the price available from the manufacturer.

(2) Best price must be determined on a unit basis without regard to package size, special packaging, labeling or identifiers on the dosage form or product or package, and must not take into account prices that are nominal in amount as described in § 447.508 of this subpart.

(3) The manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available from the manufacturer.

§ 447.506 Authorized generic drugs.

(a) *Authorized generic drug defined.* For the purposes of this subpart, an authorized generic drug means any drug sold, licensed, or marketed under an NDA approved by the FDA under section 505(c) of the FFDCA; and marketed, sold, or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand drug.

(b) *Inclusion of authorized generic drugs in AMP.* A manufacturer holding title to the original NDA of the authorized generic drug must include the sales of this drug in its AMP only when such drugs are being sold by the manufacturer holding title to the original NDA directly to a wholesaler.

(c) *Inclusion of authorized generic drugs in best price.* A manufacturer holding title to the original NDA must include best price of an authorized generic drug in its computation of best price for a single source or innovator

multiple source drug during a rebate period to any manufacturer, wholesaler, retailer, provider, HMO, nonprofit entity, or governmental entity in the United States, only when such drugs are being sold by the manufacturer holding title to the original NDA.

§ 447.508 Exclusion from best price of certain sales at a nominal price.

(a) *Exclusion from best price.* Sales of covered outpatient drugs by a manufacturer at nominal prices are excluded from best price when purchased by the following entities:

(1) A covered entity described in section 340B(a)(4) of the PHSA;

(2) An ICF/MR providing services as set forth in § 440.150 of this chapter; or

(3) A State-owned or operated nursing facility providing services as set forth in § 440.155 of this chapter.

(b) *Nonapplication.* This restriction shall not apply to sales by a manufacturer of covered outpatient drugs that are sold under a master agreement under 38, U.S.C. 8126.

§ 447.510 Requirements for manufacturers.

(a) *Quarterly reports.* A manufacturer must report product and pricing information for covered outpatient drugs to CMS not later than 30 days after the end of the rebate period. The quarterly pricing report must include:

(1) AMP, calculated in accordance with § 447.504 of this subpart;

(2) Best price, calculated in accordance with § 447.505 of this subpart;

(3) Customary prompt pay discounts, which shall be reported as an aggregate dollar amount for each covered outpatient drug at the nine-digit NDC level, provided to all wholesalers in the rebate period; and

(4) Prices that fall within the nominal price exclusion, which shall be reported as an aggregate dollar amount and shall include all sales of single source and innovator multiple source drugs to the entities listed in § 447.508(a) of this subpart for the rebate period.

(b) *Reporting revised quarterly AMP, best price, customary prompt pay discounts, or nominal prices.* (1) A manufacturer must report to CMS revisions to AMP, best price, customary prompt pay discounts, or nominal prices for a period not to exceed 12 quarters from the quarter in which the data were due.

(2) A manufacturer must report revisions to AMP, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(c) *Base date AMP report.* (1) A manufacturer may report a revised base date AMP to CMS within the first four full calendar quarters following [OFR: insert publication date of the final rule].

(2) *Recalculation of base date AMP.* (i) A manufacturer's recalculation of the base date AMP must only reflect the revisions to AMP as provided for in § 447.504 of this subpart.

(ii) A manufacturer may choose to recalculate base date AMP on a product-by-product basis.

(iii) A manufacturer must use actual and verifiable pricing records in recalculating base date AMP.

(d) *Monthly AMP*—(1) *Definition of Monthly AMP.* Monthly AMP means the AMP that is calculated on a monthly basis. A manufacturer must submit a monthly AMP to CMS not later than 30 days after the last day of each prior month.

(2) *Calculation of monthly AMP.* Monthly AMP should be calculated based on the methodology in section 447.504 of this subpart, except the period covered should be based on monthly, as opposed to quarterly, sales. The monthly AMP should be calculated based on the weighted average of prices for all the manufacturer's package sizes of each covered outpatient drug sold by the manufacturer during a month. It is calculated as net sales divided by number of units sold, excluding goods or any other items given away unless contingent on any purchase requirements. Monthly AMP should be calculated based on the best data available to the manufacturer at the time of submission. In calculating monthly AMP, a manufacturer must estimate the impact of its lagged price concessions using a 12-month rolling average to estimate the value of those discounts.

(3) *Timeframe for reporting revised monthly AMP.* A manufacturer must report to CMS revisions to monthly AMP for a period not to exceed 36 months

from the month in which the data were due.

(4) *Exception.* A manufacturer must report revisions to monthly AMP, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(5) *Terminated products.* A manufacturer must not report a monthly AMP for a terminated product beginning with the first month after the expiration date of the last lot sold.

(e) *Certification of pricing reports.* Each report submitted under paragraphs (a) through (d) of this section must be certified by one of the following:

(1) The manufacturer's chief executive officer (CEO);

(2) The manufacturer's chief financial officer (CFO);

(3) An individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO; or

(4) An individual with the directly delegated authority to perform the certification on behalf of an individual described in subsections (1) through (3).

(f) *Recordkeeping requirements.* (1) A manufacturer must retain records (written or electronic) for ten years from the date the manufacturer reports data to CMS for that rebate period. The records must include these data and any other materials from which the calculations of the AMP, the best price, customary prompt pay discounts, and nominal prices are derived, including a record of any assumptions made in the calculations. The ten-year timeframe applies to a manufacturer's quarterly and monthly submissions of pricing data, as well as any revised pricing data subsequently submitted to CMS.

(2) A manufacturer must retain records beyond the ten-year period if both of the following circumstances exist:

(i) The records are the subject of an audit or of a government investigation related to pricing data that are used in AMP, best price, customary prompt pay discounts, or nominal prices of which the manufacturer is aware.

(ii) The audit findings or investigation related to the AMP, best price, customary prompt pay discounts, or nominal price have not been resolved.

(g) *Data reporting format.* All product and pricing data, whether submitted on a quarterly or monthly basis, must be submitted to CMS in an electronic format.

§ 447.512 Drugs: Aggregate upper limits of payment.

(a) *Multiple source drugs.* Except for brand name drugs that are certified in accordance with paragraph (c) of this section, the agency payment for multiple source drugs must not exceed, in the aggregate, the amount that would result from the application of the specific limits established in accordance with § 447.514 of this subpart. If a specific limit has not been established under § 447.514 of this subpart, then the rule for ''other drugs'' set forth in paragraph (b) of this section applies.

(b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under § 447.514 of this subpart must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the—

(1) EAC plus reasonable dispensing fees established by the agency; or

(2) Providers' usual and customary charges to the general public.

(c) *Certification of brand name drugs.* (1) The upper limit for payment for multiple source drugs for which a specific limit has been established under § 447.514 of this subpart does not apply if a physician certifies in his or her own handwriting (or by an electronic alternative means approved by the Secretary) that a specific brand is medically necessary for a particular recipient.

(2) The agency must decide what certification form and procedure are used.

(3) A checkoff box on a form is not acceptable but a notation like ''brand necessary'' is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

§ 447.514 Upper limits for multiple source drugs.

(a) *Establishment and issuance of a listing.* (1) CMS will establish and issue listings that identify and set upper limits for multiple source drugs that meet the following requirements:

(i) The FDA has rated two or more drug products as therapeutically and pharmaceutically equivalent in its most current edition of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (including supplements or in successor publications), regardless of whether all such formulations are rated as such and only such formulations shall be used when determining any such upper limit.

(ii) At least two suppliers meet the criteria in paragraph (a)(1)(i) of this section.

(2) CMS publishes the list of multiple source drugs for which upper limits have been established and any revisions to the list in Medicaid Program issuances.

(b) *Specific upper limits.* The agency's payments for multiple source drugs identified and listed periodically by CMS in Medicaid Program issuances must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the State agency plus an amount established by CMS that is equal to 250 percent of the AMP (as computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent.

(c) *Ensuring a drug is for sale nationally.* To assure that a drug is for sale nationally, CMS will consider the following additional criteria:

(1) The AMP of a terminated NDC will not be used to set the Federal upper limit (FUL) beginning with the first day of the month after the actual termination date reported by the manufacturer to CMS.

(2) Except as set forth in paragraph (c)(3) of this section, the AMP of the lowest priced therapeutically and pharmaceutically equivalent drug that is not less than 40 percent of the next highest AMP will be used to establish the FUL.

(3) When the FUL group includes only the brand name drug and the first new generic or authorized generic drug which has entered the market, the criteria in paragraph (c)(2) of this section will not apply.

§ 447.516 Upper limits for drugs furnished as part of services.

The upper limits for payment for prescribed drugs in this subpart also apply to payment for drugs provided as part of skilled nursing facility services and intermediate care facility services and under prepaid capitation arrangements.

§ 447.518 State plan requirements, findings and assurances.

(a) *State plan.* The State plan must describe comprehensively the agency's payment methodology for prescription drugs.

(b) *Findings and assurances.* Upon proposing significant State plan changes in payments for prescription drugs, and at least annually for multiple source drugs and triennially for all other drugs, the agency must make the following findings and assurances:

(1) *Findings.* The agency must make the following separate and distinct findings:

(i) In the aggregate, its Medicaid expenditures for multiple source drugs, identified and listed in accordance with § 447.514(a) of this subpart, are in accordance with the upper limits specified in § 447.514(b) of this subpart; and

(ii) In the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.512 of this subpart.

(2) *Assurances.* The agency must make assurances satisfactory to CMS that the requirements set forth in §§ 447.512 and 447.514 of this subpart concerning upper limits and in paragraph (b)(1) of this section concerning agency findings are met.

(c) *Recordkeeping.* The agency must maintain and make available to CMS, upon request, data, mathematical or statistical computations, comparisons, and any other pertinent records to support its findings and assurances.

§ 447.520 FFP: Conditions relating to physician-administered drugs.

(a) No FFP is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to bill a manufacturer for rebates.

(1) As of January 1, 2006, a State must require providers to submit claims for single source, physician-administered drugs using Healthcare Common Procedure Coding System codes or NDC numbers in order to secure rebates.

(2) As of January 1, 2008, a State must require providers to submit claims for the 20 multiple source physician-administered drugs identified by the Secretary as having the highest dollar value under the Medicaid Program using NDC numbers in order to secure rebates.

(b) As of January 1, 2007, a State must require providers to submit claims for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary using NDC numbers.

(c) A State that requires additional time to comply with the requirements of this section may apply to the Secretary for an extension.

PART 455—PROGRAM INTEGRITY: MEDICAID

Sec.

Subpart A—Medicaid Agency Fraud Detection and Investigation Program

Subpart B—Disclosure of Information by Providers and Fiscal Agents

AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 43 FR 45262, Sept. 29, 1978, unless otherwise noted.

§ 455.1 Basis and scope.

This part sets forth requirements for a State fraud detection and investigation program, and for disclosure of information on ownership and control.

(a) Under the authority of sections 1902(a)(4), 1903(i)(2), and 1909 of the Social Security Act, Subpart A provides State plan requirements for the identification, investigation, and referral of suspected fraud and abuse cases. In addition, the subpart requires that the State—

(1) Report fraud and abuse information to the Department; and

(2) Have a method to verify whether services reimbursed by Medicaid were actually furnished to recipients.

(b) Subpart B implements sections 1124, 1126, 1902(a)(36), 1903(i)(2), and 1903(n) of the Act. It requires that providers and fiscal agents must agree to disclose ownership and control information to the Medicaid State agency.

[51 FR 34787, Sept. 30, 1986]

§ 455.2 Definitions.

As used in this part unless the context indicates otherwise—

Abuse means provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.